

US3562157 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:36:04

All time stamps listed in this document are displayed in GMT

US3562157

Form: Participant Creation

Generated On: 26 Nov 2020 09:36:04

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
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	True
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 09:36:04

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:36:04

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:36:04

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

Condition	FOLIC ACID DEFICIENCY
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 (7)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

Condition	RIGHT LOWER ABDOMEN PAIN
Start date (dd MMM yyyy)	UN JAN 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 (10)

Generated On: 26 Nov 2020 09:36:04

Condition	PELVIC PAIN
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:58
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	126 lb
BMI (<i>xxx.x</i>)	22.36657 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 09:36:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 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 (<i>dd MMM yyyy</i>)	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2008
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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	False
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 09:36:04

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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

What was the participant's randomization number? 113528

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 09:36:04

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 09:36:04

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 SEP 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:58
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 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)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020
Time of assessment (00:00-23:59)	17:32 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:32
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020
What was the treatment time? (00:00-23:59)	16:54 (24 HR)
Treatment Date and Time (derived)	11 SEP 2020 16:54
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 09:36:04

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

11 SEP 2020

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

16:12 (24 HR)

Collection date and time (derived)

11 SEP 2020 16:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:04

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	11 SEP 2020 16:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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 09:36:04

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 11 SEP 2020 17:35

PC Open Date & Time 11 SEP 2020 17:14

PC Close Date & Time 11 SEP 2020 19:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	11 SEP 2020 21:44
PC Open Date & Time	11 SEP 2020 20:39
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 SEP 2020 20:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020 21:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 20:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:11

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:47

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 19:16

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020 17:35

PC Open Date & Time

11 SEP 2020 17:14

PC Close Date & Time

11 SEP 2020 19:44

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

11 SEP 2020 21:45

PC Open Date & Time

11 SEP 2020 20:39

PC Close Date & Time

12 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:44

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 21:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020 20:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020 20:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020 20:48

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 SEP 2020 19:16

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:36
PC Open Date & Time	11 SEP 2020 17:14
PC Close Date & Time	11 SEP 2020 19:44

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:45
PC Open Date & Time	11 SEP 2020 20:39
PC Close Date & Time	12 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	12 SEP 2020 20:45
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	13 SEP 2020 21:06
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	14 SEP 2020 20:31
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	15 SEP 2020 20:12
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	16 SEP 2020 20:49
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	16:02 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 16:02
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 17:18
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 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)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3562157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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 OCT 2020
What was the treatment time? (00:00-23:59)	16:45 (24 HR)
Treatment Date and Time (derived)	14 OCT 2020 16:45
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

14 OCT 2020

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

16:10 (24 HR)

Collection date and time (derived)

14 OCT 2020 16:10

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:04

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:27	14 OCT 2020 16:27
Nasopharyngeal Swab 2	No		

US3562157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 17:20

PC Open Date & Time

14 OCT 2020 17:05

PC Close Date & Time

14 OCT 2020 19:35

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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 OCT 2020 21:30
PC Open Date & Time	14 OCT 2020 20:30
PC Close Date & Time	15 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	15 OCT 2020 21:17
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

97.7 °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

16 OCT 2020 21:43

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

97.6 °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

17 OCT 2020 21:51

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:32

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 22:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

97.7 °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

20 OCT 2020 21:47

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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 OCT 2020 17:20

PC Open Date & Time

14 OCT 2020 17:05

PC Close Date & Time

14 OCT 2020 19:35

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 OCT 2020 21:31

PC Open Date & Time

14 OCT 2020 20:30

PC Close Date & Time

15 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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)**

125

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)**

25

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

15 OCT 2020 21:21

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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)

2

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

16 OCT 2020 21:44

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

2

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

17 OCT 2020 21:52

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

2

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

18 OCT 2020 19:32

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

1

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

19 OCT 2020 22:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 OCT 2020 21:48

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 17:21
PC Open Date & Time	14 OCT 2020 17:05
PC Close Date & Time	14 OCT 2020 19:35

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 21:32
PC Open Date & Time	14 OCT 2020 20:30
PC Close Date & Time	15 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	15 OCT 2020 21:22
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	16 OCT 2020 21:45
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	17 OCT 2020 21:52
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	18 OCT 2020 19:33
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	19 OCT 2020 22:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 ☒

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

Yes ☐	
PC Time stamp	20 OCT 2020 21:48
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3562157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	13:03 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 13:03
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 NOV 2020
Collection time (<i>00:00-23:59</i>)	13:10 (24 HR)
Collection date and time (derived)	11 NOV 2020 13:10

US3562157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	11 NOV 2020 13:12:17
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:14:05
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

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14 JAN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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21 JAN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3562157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3562157

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:36:04

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3562157

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:36:04

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

AEID	USA-US071-2020-MRNA-1273-P30 1000002
Adverse event	PELVIC CANCER
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102) 338 of 1987

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

AEID	USA-US071-2020-MRNA-1273-P30 1000002
Adverse event	COLORECTAL CANCER
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102) 340 of 1987

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

AEID	
Adverse event	SHINGLES
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)	17 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)	07 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	342 of 1987

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:36:04

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

Yes ☒

No ☐

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	FOSAMAX
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOPOROSIS
Dose per administration	70
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

	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	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOPOROSIS
Dose per administration	4000
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

	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	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	FOLIC ACID
Prophylaxis	Yes ☐ No ☒
Indication	FOLIC ACID DEFICIENCY
Dose per administration	400
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

	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	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	MELTONIN
Prophylaxis	Yes ☐ No ☒
Indication	INSOMINIA
Dose per administration	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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	LEXAPRO
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	ESTRADIOL CREAM
Prophylaxis	Yes ☐ No ☒
Indication	POST MENOPAUSE SYNDROME
Dose per administration	10
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	2 TIMES A WEEK Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

	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	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	SUMATRIPTAN
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINE
Dose per administration	100
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
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	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	ACYCLOVIR
Prophylaxis	Yes ☐ No ☒
Indication	SHINGLES
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	FIVE TIMES A DAY Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	PROGESTERONE CAPS
Prophylaxis	Yes ☐ No ☒
Indication	POST MENOPAUSE SYNDROME
Dose per administration	100
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

	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)		14 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	☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	LIDOCAINE 2% CREAM
Prophylaxis	Yes ☐ No ☒
Indication	SHINGLES
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATOR
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	FLU PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
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 ☒

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

Name of Medication	VITAMIN B12
Prophylaxis	Yes ☐ No ☒
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	5000
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 ☐

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

	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	☒

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:36:04

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3562157

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:36:04

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

US3562157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:36:04

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 ☐

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

SAEID	USA-US071-2020-MRNA-1273-P301000002
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:36:04

SAEID	USA-US071-2020-MRNA-1273-P301000002
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 22:58
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:36:04

SAEID	USA-US071-2020-MRNA-1273-P301000002
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/NOV/2020 14:25
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:36:04

SAEID	USA-US071-2020-MRNA-1273-P301000002
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:56
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

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:36:04

SAEID	USA-US071-2020-MRNA-1273-P301000002
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/NOV/2020 15:53
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

US3562157 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562157

Form: Participant Creation

Generated On: 26 Nov 2020 09:36:04

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:45:50
User entered 'US3562157'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:34:57

US3562157

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:47:50
	(b) (4)	

US3562157

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:18
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:35:02

US3562157

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:18
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4)	13 Sep 2020 21:47:50
	(b) (4)	

US3562157

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	13 Sep 2020 21:47:50

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:35:06

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '62'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	13 Sep 2020 21:49:56

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '62'	System	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered 'Female (F)'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '1'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '1'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:36:04

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:50:59
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:56
	(b) (4)	

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered 'No (N)'	(b) (4), (b) (6)	12 Sep 2020 00:18:34

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:51:20
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 22:35:02

US3562157

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:36:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:54:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:36:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:54:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:47:57
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:49:07
User entered 'osteoporosis'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2015'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:14
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:14

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:54:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:54:20
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:49:08
User entered 'vitamin d deficiency'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2015'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:30
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:30

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:49:07
User entered 'insomnia'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2008'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:44
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:44

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:49:39
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:49:07
User entered 'post menopause'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2008'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:48:59
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:48:59

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:50:11
User entered 'migraine headaches'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2008'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:17
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2008'	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:49:17

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Folate deficiency, LLT: Folic acid deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 21:51:39
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:50:11
User entered 'folic acid deficiency'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2019'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:49:32
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2019'	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:49:32

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:06:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:06:51
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 15:36:03
User entered 'hypercholesterolemia'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un Jun 2020'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:26
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2020'	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:35:26

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 15:36:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 15:36:53
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 15:36:03
User entered 'anxiety'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un UNK 2018'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:38
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:35:38

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:11:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:11:52
Data point term sent to Coder	System	17 Nov 2020 15:36:04
User entered 'right lower abdomen pain'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un Jan 2019'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:35:55
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:35:55

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Reproductive tract disorders NEC, HLT: Reproductive tract signs and symptoms NEC, PT: Pelvic pain, LLT: Pelvic pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 15:37:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 15:37:48
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 15:37:05
User entered 'pelvic pain'	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'un Dec 2019'	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered empty.	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:44:16
User entered '0'	Dhwani Shah (b) (4)	17 Nov 2020 15:36:18
	(b) (4)	

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'Dec 2019'	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 15:36:18

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered '11 Sep 2020'	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:46:34
User closed query 'Please confirm time. Per source, 15:58 is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:46:28
Query 'Please confirm time. Per source, 15:58 is recorded. Please update as applicable. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	18 Nov 2020 22:23:49
	(b) (4)	
DataPoint Un-verified.	Dhwani Shah (b) (4)	18 Nov 2020 22:23:42
	(b) (4)	
User entered '15:58' reason for change: Data Entry Error	Dhwani Shah (b) (4)	18 Nov 2020 22:23:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User opened query 'Please confirm time. Per source, 15:58 is recorded. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:46:57
User entered '16:02'	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:58'	System	18 Nov 2020 22:23:42
User entered '11 Sep 2020 16:02'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered '63' in	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
DataPoint set to visible.	(b) (4) System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered '126' lb	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
DataPoint set to visible.	(b) (4) System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '22.36657'	System	20 Oct 2020 14:01:10
DataPoint set to visible.	System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	20 Oct 2020 14:01:10
DataPoint set to visible.	System	12 Sep 2020 00:18:41

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered empty.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered empty.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:17
User entered missing code ND - Not Done.	Dhwani Shah (b) (4)	20 Oct 2020 14:01:10
	(b) (4)	

US3562157

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Oct 2020 14:01:10

US3562157

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:05
	(b) (4)	

US3562157

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:52
User entered '11 Sep 2020'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:05
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered '11 Sep 2020'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

[Date of surgery unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered 'un UNK 2008'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:36:04

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:01
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:50:41
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered '1'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

Other

Audit	User	Time (GMT)
User entered '0'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:51:29

US3562157

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:36:04

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:52:22
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:51:29
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:56
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:45
User entered '11 Sep 2020'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:56
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:54:45
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:56
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Sep 2020 21:51:56

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 23:29:15

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered '113528'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 23:29:15

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 23:29:15

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:43
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:43
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:43
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:43
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:55:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:51:43
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User closed query 'Please complete Vital Sign - Dosing eCRF (next eCRF). ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:47:00
Query 'Please complete Vital Sign - Dosing eCRF (next eCRF). ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	18 Nov 2020 22:28:08
User opened query 'Please complete Vital Sign - Dosing eCRF (next eCRF). ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:56:56
User entered 'No (N)'	(b) (4)	18 Nov 2020 16:55:08
Amendment Manager: DataPoint set to visible.	Dhwani Shah (b) (4)	18 Nov 2020 16:47:41
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	19 Sep 2020 09:04:38
	System	19 Sep 2020 09:04:37

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:04

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:04

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:04

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:04

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:26:30
User entered '11 Sep 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	18 Nov 2020 22:26:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:25:21
User entered '18 Nov 2020'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:26:30
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:25:21
User entered '15:58'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 15:58'	System	18 Nov 2020 22:26:30
User entered '18 Nov 2020 15:58'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '16'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '122'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '74'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:04

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:36:04

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:26:30
User entered '11 Sep 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	18 Nov 2020 22:26:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Nov 2020 22:25:21
User entered '18 Nov 2020'	Dhwani Shah (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '17:32'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:32'	System	18 Nov 2020 22:26:30
User entered '18 Nov 2020 17:32'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '14'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '105'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '71'	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 22:25:21

US3562157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:07
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:03
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:07
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:52:03
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered '16:54'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:54'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:57:54
User entered 'ONCE'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 00:19:07

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:20
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered '11 Sep 2020'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:20
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:16
User entered '16:12'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:20
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:12'	System	13 Sep 2020 21:52:20

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered '11 Sep 2020'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:40
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:40
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered '16:10'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:40
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:10'	System	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:40
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:32
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:52:40
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:52:40

US3562157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:58:41
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:47
	(b) (4)	

US3562157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:52:47

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:33:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8'	System	12 Sep 2020 00:35:07
User entered 'Yes (Y)'	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:34:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8'	System	12 Sep 2020 00:35:07
User entered '98.0'	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:34:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8'	System	12 Sep 2020 00:35:07
User entered 'No (N)'	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:01', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd789eac3-a84b-49db-808b-ff4d2efe19f8'	System	12 Sep 2020 00:35:07
User entered '11 Sep 2020 17:35'	System	12 Sep 2020 00:35:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:14'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 19:44'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:43:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered 'Yes (Y)'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:43:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered '98.0'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:43:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered 'No (N)'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '59ffcf7-6ba8-4fb9-a8e8-24edfb5f4ecd'	System	12 Sep 2020 04:44:15
User entered '11 Sep 2020 21:44'	System	12 Sep 2020 04:44:15

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 20:39'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 2'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:41:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered 'Yes (Y)'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:42:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered '98.0'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered 'Yes (Y)'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'sw pt and added con med line 8' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 05:36:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'sw pt and added con med line 8' (Site from System).	Dhwani Shah (b) (4)	26 Sep 2020 17:43:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 03:43:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:42:46', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered '1'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:42:46', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered '0'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'eb225a75-d5e4-4c52-8faa-e2d7006b5d51'	System	13 Sep 2020 03:43:57
User entered '12 Sep 2020 20:43'	System	13 Sep 2020 03:43:57

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 3'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:04:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977'	System	14 Sep 2020 04:05:14
User entered 'Yes (Y)'	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:04:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977'	System	14 Sep 2020 04:05:14
User entered '98.0'	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977'	System	14 Sep 2020 04:05:14
User entered 'No (N)'	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'b3ef43da-439e-49f5-a70c-aafb685c9977'	System	14 Sep 2020 04:05:14
User entered '13 Sep 2020 21:05'	System	14 Sep 2020 04:05:14

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 4'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98'	System	15 Sep 2020 03:30:30
User entered 'Yes (Y)'	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98'	System	15 Sep 2020 03:30:30
User entered '98.0'	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98'	System	15 Sep 2020 03:30:30
User entered 'No (N)'	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5ef55c79-0dc8-4fd5-8e24-74c4bf49ca98'	System	15 Sep 2020 03:30:30
User entered '14 Sep 2020 20:30'	System	15 Sep 2020 03:30:30

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 5'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6'	System	16 Sep 2020 03:11:51
User entered 'Yes (Y)'	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6'	System	16 Sep 2020 03:11:51
User entered '97.6'	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6'	System	16 Sep 2020 03:11:51
User entered 'No (N)'	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5631e5d0-d83c-4d48-b7eb-9cf4a2e13ce6'	System	16 Sep 2020 03:11:51
User entered '15 Sep 2020 20:11'	System	16 Sep 2020 03:11:51

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 6'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:31', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e'	System	17 Sep 2020 03:47:54
User entered 'Yes (Y)'	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e' User entered '97.9'	System	17 Sep 2020 03:47:54
	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e'	System	17 Sep 2020 03:47:54
User entered 'No (N)'	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:50', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c4ace321-0203-4dee-9721-7292534efb7e' User entered '16 Sep 2020 20:47'	System	17 Sep 2020 03:47:54
	System	17 Sep 2020 03:47:54

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 7'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19'	System	18 Sep 2020 02:16:29
User entered 'Yes (Y)'	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19'	System	18 Sep 2020 02:16:29
User entered '98.2'	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19'	System	18 Sep 2020 02:16:29
User entered 'No (N)'	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4080a848-69f5-490a-8d40-67a80925dc19'	System	18 Sep 2020 02:16:29
User entered '17 Sep 2020 19:16'	System	18 Sep 2020 02:16:29

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered 'None (1)'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered 'No (N)'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered 'No (N)'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered 'None (1)'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:35:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8a6c76e5-0e5e-4212-8ae9-2dc5f2221e08'	System	12 Sep 2020 00:35:50
User entered '11 Sep 2020 17:35'	System	12 Sep 2020 00:35:50

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:14'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 19:44'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:31', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'No (N)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:47', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'No (N)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:44:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered 'None (1)'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:03', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '13289dd5-d80a-4cf8-bf26-e152f427ef02'	System	12 Sep 2020 04:45:11
User entered '11 Sep 2020 21:45'	System	12 Sep 2020 04:45:11

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 20:39'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 2'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:34', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f'	System	13 Sep 2020 03:44:18
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f'	System	13 Sep 2020 03:44:18
User entered 'No (N)'	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:51', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f'	System	13 Sep 2020 03:44:18
User entered 'No (N)'	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:43:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f'	System	13 Sep 2020 03:44:18
User entered 'None (1)'	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:44:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '077ec4d8-2602-4717-926c-8270b560b26f' User entered '12 Sep 2020 20:44'	System	13 Sep 2020 03:44:18
	System	13 Sep 2020 03:44:18

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 3'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered 'No (N)'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered 'No (N)'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered 'None (1)'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '04f1d3a4-2953-4ba7-8840-5839444f9e74'	System	14 Sep 2020 04:05:57
User entered '13 Sep 2020 21:05'	System	14 Sep 2020 04:05:57

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 4'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:46', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered 'No (N)'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered 'No (N)'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:30:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered 'None (1)'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6b84dd05-cde4-47d4-9768-131d5766043c'	System	15 Sep 2020 03:31:10
User entered '14 Sep 2020 20:31'	System	15 Sep 2020 03:31:10

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 5'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered 'None (1)'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:11:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered 'No (N)'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered 'No (N)'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered 'None (1)'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5f721a77-369e-414a-ad55-effd1ec0ff50'	System	16 Sep 2020 03:12:24
User entered '15 Sep 2020 20:12'	System	16 Sep 2020 03:12:24

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 6'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:47:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68'	System	17 Sep 2020 03:48:23
User entered 'None (1)'	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:01', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68'	System	17 Sep 2020 03:48:23
User entered 'No (N)'	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68'	System	17 Sep 2020 03:48:23
User entered 'No (N)'	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68'	System	17 Sep 2020 03:48:23
User entered 'None (1)'	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd5049ade-f843-47c4-ad56-d004b029bb68'	System	17 Sep 2020 03:48:23
User entered '16 Sep 2020 20:48'	System	17 Sep 2020 03:48:23

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 7'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'None (1)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'No (N)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'No (N)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered 'None (1)'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:48', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8f31b557-ead9-46ca-9b8a-ef0c23eb4a43'	System	18 Sep 2020 02:16:52
User entered '17 Sep 2020 19:16'	System	18 Sep 2020 02:16:52

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'None (0)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'None (0)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'None (0)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'None (0)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'None (0)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'None (0)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered 'No (N)'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T17:36:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '26fa8cce-abd9-41e5-bc90-ce2193a0b5e3'	System	12 Sep 2020 00:36:38
User entered '11 Sep 2020 17:36'	System	12 Sep 2020 00:36:38

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:14'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 19:44'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'None (0)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'None (0)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'None (0)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'None (0)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'None (0)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'None (0)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered 'No (N)'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-11T21:45:55', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1a807ab6-d4f9-4241-919c-81404cd3855e'	System	12 Sep 2020 04:45:56
User entered '11 Sep 2020 21:45'	System	12 Sep 2020 04:45:56

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 20:39'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 2'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'None (0)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'None (0)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1' User entered 'None (0)'	System	13 Sep 2020 03:45:52
	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'None (0)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'No interference with activity (1)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:40', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered 'No (N)'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-12T20:45:50', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '70334a6e-d97d-4a9b-94b1-c1dea56a67c1'	System	13 Sep 2020 03:45:52
User entered '12 Sep 2020 20:45'	System	13 Sep 2020 03:45:52

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 3'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:05:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'None (0)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'None (0)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'None (0)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'None (0)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'None (0)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'None (0)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered 'No (N)'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-13T21:06:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '77898bef-4636-4200-ba95-159bdad13647'	System	14 Sep 2020 04:06:39
User entered '13 Sep 2020 21:06'	System	14 Sep 2020 04:06:39

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 4'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'None (0)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'None (0)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'None (0)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:22', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'None (0)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'None (0)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'None (0)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered 'No (N)'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-14T20:31:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '344ebc7b-c610-41b3-9cc1-7a3f361e4c79'	System	15 Sep 2020 03:31:53
User entered '14 Sep 2020 20:31'	System	15 Sep 2020 03:31:53

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 5'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'None (0)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'None (0)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:31', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'None (0)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'None (0)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'None (0)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'None (0)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered 'No (N)'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-15T20:12:58', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '2e405f04-b574-43d3-a026-e8885849e65c'	System	16 Sep 2020 03:13:01
User entered '15 Sep 2020 20:12'	System	16 Sep 2020 03:13:01

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 6'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba'	System	17 Sep 2020 03:49:28
User entered 'None (0)'	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffede81-b939-4424-ada0-9ee532b22aba'	System	17 Sep 2020 03:49:28
User entered 'None (0)'	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffede81-b939-4424-ada0-9ee532b22aba' User entered 'None (0)'	System	17 Sep 2020 03:49:28
	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba'	System	17 Sep 2020 03:49:28
User entered 'None (0)'	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:48:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffe81-b939-4424-ada0-9ee532b22aba'	System	17 Sep 2020 03:49:28
User entered 'None (0)'	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:49:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffede81-b939-4424-ada0-9ee532b22aba'	System	17 Sep 2020 03:49:28
User entered 'No (N)'	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-16T20:49:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'cffede81-b939-4424-ada0-9ee532b22aba'	System	17 Sep 2020 03:49:28
User entered '16 Sep 2020 20:49'	System	17 Sep 2020 03:49:28

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 7'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'None (0)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:16:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'None (0)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'None (0)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'None (0)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'None (0)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'None (0)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered 'No (N)'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-09-17T19:17:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5941e977-b3c3-47c0-a9ed-4470a683f303'	System	18 Sep 2020 02:17:19
User entered '17 Sep 2020 19:17'	System	18 Sep 2020 02:17:19

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 00:19:07

US3562157

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:30
	(b) (4)	

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered '18 Sep 2020'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:30
	(b) (4)	

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:30
	(b) (4)	

US3562157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:00:45
User entered empty.	Dhwani Shah (b) (4)	25 Sep 2020 23:31:30
	(b) (4)	

US3562157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:00:56
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:36
	(b) (4)	

US3562157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 23:31:36

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:50
	(b) (4)	

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered '25 Sep 2020'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:50
	(b) (4)	

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:50
	(b) (4)	

US3562157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:01:23
User entered empty.	Dhwani Shah (b) (4)	25 Sep 2020 23:31:50
	(b) (4)	

US3562157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:01:32
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	25 Sep 2020 23:31:56
	(b) (4)	

US3562157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 23:31:56

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	02 Oct 2020 23:47:55
	(b) (4)	

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered '2 Oct 2020'	Dhwani Shah (b) (4)	02 Oct 2020 23:47:55
	(b) (4)	

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	02 Oct 2020 23:47:55
	(b) (4)	

US3562157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:02:50
User entered empty.	Dhwani Shah (b) (4)	02 Oct 2020 23:47:55
	(b) (4)	

US3562157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:02:59
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	02 Oct 2020 23:48:03
	(b) (4)	

US3562157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 23:48:03

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:06
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	15 Oct 2020 17:31:28
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:06
User entered '14 Oct 2020'	Dhwani Shah (b) (4)	15 Oct 2020 17:31:28
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:06
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4)	15 Oct 2020 17:31:28
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Oct 2020 17:31:28

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '14 Oct 2020'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '16:02'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 16:02'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '98.3' F	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Oral (Oral)'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered empty.	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '69'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '16'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '106'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '68'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:36:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '14 Oct 2020'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '17:18'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 17:18'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '98.3' F	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered 'Oral (Oral)'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered empty.	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '66'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '16'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '122'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:05:58
User entered '74'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:31
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:36:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 17:36:31

US3562157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:27:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:27:43
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	18 Nov 2020 17:06:33
User entered 'No (N)'	[REDACTED] Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:36

US3562157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:27:43
User entered '14 Oct 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	18 Nov 2020 22:27:43
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	18 Nov 2020 17:06:33
User entered empty.	[REDACTED] Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:36:36

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered '16:45'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 16:45'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:07:14
User entered 'ONCE'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 23:49:11

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:55
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 12:54:12
	(b) (4), (b) (6)	18 Nov 2020 17:08:08
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'per protocol immunogenicity sample must be collected at each visit. all samples send to PPD central lab as well ! Submitted DCF 2 weeks before and PPD need to update from their side ! Site has confirmation that PPD central lab received all samples for visit 1 and visit 2 ' (Site from DM).	Dhwani Shah (b) (4)	26 Oct 2020 20:25:29
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:40:31
User entered '14 Oct 2020'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:55

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:08
User entered '16:10'	Dhwani Shah (b) (4)	15 Oct 2020 17:36:55
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 16:10'	System	15 Oct 2020 17:36:55

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered '14 Oct 2020'	Dhwani Shah (b) (4)	15 Oct 2020 17:37:07
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	15 Oct 2020 17:37:07
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered '16:27'	Dhwani Shah (b) (4)	15 Oct 2020 17:37:07
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 16:27'	System	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered 'No (N)'	Dhwani Shah (b) (4)	15 Oct 2020 17:37:07
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:08:56
User entered empty.	Dhwani Shah (b) (4)	15 Oct 2020 17:37:07
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 17:37:07

US3562157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:09:09
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	15 Oct 2020 17:37:11
	(b) (4)	

US3562157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:37:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:19:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf'	System	15 Oct 2020 00:20:10
User entered 'Yes (Y)'	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:19:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf'	System	15 Oct 2020 00:20:10
User entered '98.3'	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf'	System	15 Oct 2020 00:20:10
User entered 'No (N)'	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8ae2e186-4bce-4597-b3cc-206c9c72bbbf' User entered '14 Oct 2020 17:20'	System	15 Oct 2020 00:20:10
	System	15 Oct 2020 00:20:10

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 17:05'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 19:35'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:10', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered 'Yes (Y)'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:16', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered '98.6'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered 'No (N)'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:29', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'feb8ce87-4a05-4842-af38-e76c84b852a2'	System	15 Oct 2020 04:30:32
User entered '14 Oct 2020 21:30'	System	15 Oct 2020 04:30:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 20:30'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 2'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:38', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4'	System	16 Oct 2020 04:17:15
User entered 'Yes (Y)'	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered '98.8'	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:51', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4'	System	16 Oct 2020 04:17:15
User entered 'Yes (Y)'	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated con med 12' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 07:09:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:02
User entered '1'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:16:59', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered '0'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:17:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '675ba10e-e5a2-4cf5-9512-572e1fd3d6e4' User entered '15 Oct 2020 21:17'	System	16 Oct 2020 04:17:15
	System	16 Oct 2020 04:17:15

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 3'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37'	System	17 Oct 2020 04:43:47
User entered 'Yes (Y)'	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37'	System	17 Oct 2020 04:43:47
User entered '97.7'	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37'	System	17 Oct 2020 04:43:47
User entered 'No (N)'	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e2daabe2-b07a-4196-b351-e3928618fd37'	System	17 Oct 2020 04:43:47
User entered '16 Oct 2020 21:43'	System	17 Oct 2020 04:43:47

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 4'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f'	System	18 Oct 2020 04:51:32
User entered 'Yes (Y)'	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f'	System	18 Oct 2020 04:51:32
User entered '97.6'	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f'	System	18 Oct 2020 04:51:32
User entered 'No (N)'	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8897d32d-cbc3-4980-b618-ccf3ba8c544f' User entered '17 Oct 2020 21:51'	System	18 Oct 2020 04:51:32

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 5'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:01', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c'	System	19 Oct 2020 02:32:17
User entered 'Yes (Y)'	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c' User entered '97.9'	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c'	System	19 Oct 2020 02:32:17
User entered 'No (N)'	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9f9bde2-e8ba-49f7-8f1e-10cfbdf9475c'	System	19 Oct 2020 02:32:17
User entered '18 Oct 2020 19:32'	System	19 Oct 2020 02:32:17

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 6'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered 'Yes (Y)'	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered '98.7'	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa'	System	20 Oct 2020 05:00:27
User entered 'No (N)'	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '21534e09-3e3d-4a72-b413-2f728305abfa' User entered '19 Oct 2020 22:00'	System	20 Oct 2020 05:00:27
	System	20 Oct 2020 05:00:27

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 7'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:29', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered 'Yes (Y)'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:34', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered '97.7'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered 'No (N)'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e9ba9f35-821b-4fec-930d-158340e2f4d7'	System	21 Oct 2020 04:47:46
User entered '20 Oct 2020 21:47'	System	21 Oct 2020 04:47:46

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered 'None (1)'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered 'No (N)'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:30', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered 'No (N)'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered 'None (1)'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:20:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '4b41b15e-c307-48a5-a68c-b48ea8527b06'	System	15 Oct 2020 00:20:46
User entered '14 Oct 2020 17:20'	System	15 Oct 2020 00:20:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 17:05'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 19:35'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:47', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'No (N)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:30:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'No (N)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered 'None (1)'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:42', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f09712c4-bc77-4690-b5c4-159434694e72'	System	15 Oct 2020 04:31:45
User entered '14 Oct 2020 21:31'	System	15 Oct 2020 04:31:45

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 20:30'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 2'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:17:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e'	System	16 Oct 2020 04:21:37
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:17:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e'	System	16 Oct 2020 04:21:37
User entered 'Yes (Y)'	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:20:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered '125'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:20:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e'	System	16 Oct 2020 04:21:37
User entered 'Yes (Y)'	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:21:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e' User entered '25'	System	16 Oct 2020 04:21:37
	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:21:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e'	System	16 Oct 2020 04:21:37
User entered 'None (1)'	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:21:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd45c4796-5a35-481c-8013-77ad3af7eb7e'	System	16 Oct 2020 04:21:37
User entered '15 Oct 2020 21:21'	System	16 Oct 2020 04:21:37

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 3'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:43:51', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c'	System	17 Oct 2020 04:44:46
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c'	System	17 Oct 2020 04:44:46
User entered 'No (N)'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c'	System	17 Oct 2020 04:44:46
User entered 'Yes (Y)'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c' User entered '2'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:30', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c'	System	17 Oct 2020 04:44:46
User entered 'None (1)'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '1d7897da-85dc-4148-b44b-516b14ceeb6c'	System	17 Oct 2020 04:44:46
User entered '16 Oct 2020 21:44'	System	17 Oct 2020 04:44:46

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 4'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867'	System	18 Oct 2020 04:52:08
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867'	System	18 Oct 2020 04:52:08
User entered 'No (N)'	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:48', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867'	System	18 Oct 2020 04:52:08
User entered 'Yes (Y)'	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:51:54', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867' User entered '2'	System	18 Oct 2020 04:52:08
	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867'	System	18 Oct 2020 04:52:08
User entered 'None (1)'	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '03896e6d-8778-4cd0-aa79-a277a76cc867'	System	18 Oct 2020 04:52:08
User entered '17 Oct 2020 21:52'	System	18 Oct 2020 04:52:08

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 5'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacac'	System	19 Oct 2020 02:33:00
User entered 'None (1)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacac'	System	19 Oct 2020 02:33:00
User entered 'No (N)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:33', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacac'	System	19 Oct 2020 02:33:00
User entered 'Yes (Y)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:39', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacac' User entered '2'	System	19 Oct 2020 02:33:00
	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacac'	System	19 Oct 2020 02:33:00
User entered 'None (1)'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:32:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'f886387f-0866-4dbe-8eef-a74a46dfacac'	System	19 Oct 2020 02:33:00
User entered '18 Oct 2020 19:32'	System	19 Oct 2020 02:33:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 6'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:29', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered 'None (1)'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb'	System	20 Oct 2020 05:01:00
User entered 'No (N)'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:35', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered 'Yes (Y)'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:44', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered '1'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:47', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb'	System	20 Oct 2020 05:01:00
User entered 'None (1)'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:00:55', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '9ba6fc85-ff78-404c-afa2-672a895076fb' User entered '19 Oct 2020 22:00'	System	20 Oct 2020 05:01:00

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 7'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a'	System	21 Oct 2020 04:48:15
User entered 'None (1)'	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:47:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a'	System	21 Oct 2020 04:48:15
User entered 'No (N)'	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a'	System	21 Oct 2020 04:48:15
User entered 'No (N)'	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a'	System	21 Oct 2020 04:48:15
User entered 'None (1)'	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '45d1d8a8-b965-4249-82d9-65be3f52690a'	System	21 Oct 2020 04:48:15
User entered '20 Oct 2020 21:48'	System	21 Oct 2020 04:48:15

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:08', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'None (0)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'None (0)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'None (0)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:18', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'None (0)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'None (0)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:24', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'None (0)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered 'No (N)'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T17:21:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '6969f3f4-8c3c-4d4a-8cba-cf160e0a7458'	System	15 Oct 2020 00:21:41
User entered '14 Oct 2020 17:21'	System	15 Oct 2020 00:21:41

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 17:05'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 19:35'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:48', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'None (0)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:52', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'None (0)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:31:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'None (0)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'None (0)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'None (0)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'None (0)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered 'No (N)'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-14T21:32:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '356b962e-b547-4f2a-b132-c5c371bdc330'	System	15 Oct 2020 04:32:29
User entered '14 Oct 2020 21:32'	System	15 Oct 2020 04:32:29

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 20:30'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 2'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'No interference with activity (1)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'Some interference with activity (2)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'None (0)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'None (0)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:19', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'None (0)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:22', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'None (0)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered 'No (N)'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-15T21:22:41', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '05839fd1-31b5-40c9-9c46-0e20bba61015'	System	16 Oct 2020 04:22:44
User entered '15 Oct 2020 21:22'	System	16 Oct 2020 04:22:44

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 3'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'None (0)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:53', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'None (0)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:44:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'None (0)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'None (0)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'None (0)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'None (0)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79'	System	17 Oct 2020 04:45:19
User entered 'No (N)'	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-16T21:45:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'e24f8d61-f6b2-4ea5-a24d-657fe776eb79' User entered '16 Oct 2020 21:45'	System	17 Oct 2020 04:45:19
	System	17 Oct 2020 04:45:19

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 4'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'None (0)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:14', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'None (0)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:18', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'None (0)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'None (0)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'None (0)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'None (0)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered 'No (N)'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-17T21:52:34', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'c67d02c2-f0b2-4ab4-9e52-f9398dd58b73'	System	18 Oct 2020 04:52:37
User entered '17 Oct 2020 21:52'	System	18 Oct 2020 04:52:37

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 5'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'None (0)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:02', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'None (0)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'None (0)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:07', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'None (0)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'None (0)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:12', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'None (0)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:15', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered 'No (N)'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-18T19:33:23', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '5dbb89a6-6d72-4bd4-bff0-09f7a536c167'	System	19 Oct 2020 02:33:26
User entered '18 Oct 2020 19:33'	System	19 Oct 2020 02:33:26

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 6'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:00', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'None (0)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:04', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'None (0)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:06', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'None (0)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:09', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'None (0)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:11', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'None (0)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:13', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'None (0)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:20', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348'	System	20 Oct 2020 05:01:32
User entered 'No (N)'	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-19T22:01:28', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '8b549b47-5af5-43d2-8e5a-632121ded348' User entered '19 Oct 2020 22:01'	System	20 Oct 2020 05:01:32
	System	20 Oct 2020 05:01:32

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 23:49:11
User entered 'Day 7'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'None (0)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:21', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'None (0)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:25', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'None (0)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:27', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'None (0)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:30', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'None (0)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:32', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'None (0)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:36', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered 'No (N)'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-10-20T21:48:45', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '742fbe38-e029-48a5-90c9-33f77a7a1a25'	System	21 Oct 2020 04:48:48
User entered '20 Oct 2020 21:48'	System	21 Oct 2020 04:48:48

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 23:49:11

US3562157

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:36:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 23:49:11

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:13:29
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	22 Oct 2020 16:31:36
	(b) (4)	

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:13:29
User entered '22 Oct 2020'	Dhwani Shah (b) (4)	22 Oct 2020 16:31:36
	(b) (4)	

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:13:29
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	22 Oct 2020 16:31:36
	(b) (4)	

US3562157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:13:29
User entered empty.	Dhwani Shah (b) (4)	22 Oct 2020 16:31:36
	(b) (4)	

US3562157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:13:38
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	22 Oct 2020 16:31:40
	(b) (4)	

US3562157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 16:31:40

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:14:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	28 Oct 2020 22:40:33
	(b) (4)	

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:14:08
User entered '28 Oct 2020'	Dhwani Shah (b) (4)	28 Oct 2020 22:40:33
	(b) (4)	

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:14:08
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	28 Oct 2020 22:40:33
	(b) (4)	

US3562157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:14:08
User entered empty.	Dhwani Shah (b) (4)	28 Oct 2020 22:40:33
	(b) (4)	

US3562157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:14:17
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	28 Oct 2020 22:40:36
	(b) (4)	

US3562157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 22:40:36

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:18
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 20:16:57
	(b) (4)	

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:18
User entered '05 Nov 2020'	Dhwani Shah (b) (4)	11 Nov 2020 20:16:57
	(b) (4)	

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:18
User entered 'Contact Made (CONTACT MADE)'	Dhwani Shah (b) (4)	11 Nov 2020 20:16:57
	(b) (4)	

US3562157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:36:04

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:18
User entered empty.	Dhwani Shah (b) (4)	11 Nov 2020 20:16:57
	(b) (4)	

US3562157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:27
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 20:17:00
	(b) (4)	

US3562157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 20:17:00

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:19:21
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:24
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:19:21
User entered '11 Nov 2020'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:24
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:19:21
User entered 'Clinic (Clinic)'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:24
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:36:04

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	11 Nov 2020 23:06:24

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '11 Nov 2020'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '13:03'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Nov 2020 13:03'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '98.9' F	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered 'Oral (Oral)'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered empty.	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '72'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '14'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '105'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:41:44
User entered '71'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:46
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:36:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 23:06:46

US3562157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:11
User closed query 'Please confirm response. Per source, symptom directed PE was not done. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:48:04
Query 'Please confirm response. Per source, symptom directed PE was not done. Please update as applicable. ' answered with 'physical was done please see progress note Thank you' (Site from CRA).	Dhwani Shah (b) (4)	18 Nov 2020 22:23:15
	(b) (4)	
User opened query 'Please confirm response. Per source, symptom directed PE was not done. Please update as applicable. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:20:54
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:52
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:36:04

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:11
User entered '11 Nov 2020'	Dhwani Shah (b) (4)	11 Nov 2020 23:06:52
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:21:19
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 23:07:04
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:21:19
User entered '11 Nov 2020'	Dhwani Shah (b) (4)	11 Nov 2020 23:07:04
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:21:19
User entered '13:10'	Dhwani Shah (b) (4)	11 Nov 2020 23:07:04
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '11 Nov 2020 13:10'	System	11 Nov 2020 23:07:04

US3562157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:21:28
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	11 Nov 2020 23:07:07
	(b) (4)	

US3562157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:36:04

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 23:07:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered 'Day 64'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:26', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'Yes (Y)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

Have you been exposed to someone with 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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:33', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'No (N)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:37', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'No (N)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:49', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'Yes (Y)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:11:56', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36'	System	11 Nov 2020 20:12:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-11T13:12:17', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: '3a69b2f9-5777-47a9-ab61-5c579b57df36' User entered '11 Nov 2020 13:12:17'	System	11 Nov 2020 20:12:27
	System	11 Nov 2020 20:12:27

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered '11 Nov 2020 00:01'	System	12 Sep 2020 00:19:07

US3562157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:19:07
User entered '15 Nov 2020 23:59'	System	12 Sep 2020 00:19:07

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-22T09:13:50', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd566062e-b03a-4914-ab1c-0ace301e1e54'	System	22 Nov 2020 16:14:08
User entered 'No (N)'	System	22 Nov 2020 16:14:08

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

Have you been exposed to someone with 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 (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-22T09:13:57', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd566062e-b03a-4914-ab1c-0ace301e1e54'	System	22 Nov 2020 16:14:08
User entered 'No (N)'	System	22 Nov 2020 16:14:08

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BF6A449-59FC-4C41-80ED-FC7F88A61818)', Time: '2020-11-22T09:14:05', User OID: 'PatientReportedOutcome (US3562157)', ODM File OID: 'd566062e-b03a-4914-ab1c-0ace301e1e54' User entered '22 Nov 2020 09:14:05'	System	22 Nov 2020 16:14:08
	System	22 Nov 2020 16:14:08

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:58:03

US3562157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:36:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:58:03
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:58:03

US3562157

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:36:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	06 Nov 2020 00:48:06
	(b) (4)	
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:52:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:04
User entered 'USA-US071-2020-mRNA-1273-P301000002'	System	06 Nov 2020 22:57:56
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 22:57:56

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms unspecified malignancy and site unspecified NEC, PT: Pelvic neoplasm, LLT: Pelvic neoplasm - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 05:52:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 05:52:51
Data point term sent to Coder	System	06 Nov 2020 00:50:04
User entered 'PELVIC CANCER'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '04 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	10 Nov 2020 21:04:05
User entered '04 Oct 2020'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 15:31:55 06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Grade 4 (Grade 4)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '1'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 00:50:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 00:50:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	06 Nov 2020 00:50:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Nov 2020 00:50:03
	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '1'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:31:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	06 Nov 2020 00:50:03
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:36:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:35:38
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:36:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:36:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'still waiting for medical records, will updated once receive more info ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 17:58:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'still waiting for medical records, will updated once receive more info ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 17:58:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	13 Nov 2020 15:31:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	13 Nov 2020 15:31:20
User entered 'PATENT WAS REFERED TO ONCOLOGIST'	Dhwani Shah (b) (4) (b) (4)	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:36:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 00:50:03

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:23:35
User entered	(b) (4), (b) (6)	10 Nov 2020 14:16:07
'USA-US071-2020-mRNA-1273-P301000002'		

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colorectal cancer, LLT: Colorectal cancer - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 21:48:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 21:48:40
Data point term sent to Coder	System	11 Nov 2020 21:47:30
User entered 'colorectal cancer' reason for change: Data Entry Error	Dhwani Shah (b) (4)	11 Nov 2020 21:46:39
	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 21:46:29
User closed query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Benign colonic neoplasm, Malignant neoplasm of colon etc)' (Site from System).	System	11 Nov 2020 21:46:13
Query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Benign colonic neoplasm, Malignant neoplasm of colon etc)' answered with 'will provide more info once received medical records ' (Site from System).	Dhwani Shah (b) (4)	11 Nov 2020 21:46:13
	(b) (4)	
User opened query 'CDM Coding, please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Benign colonic neoplasm, Malignant neoplasm of colon etc)' (Site from System).	Coder Import (b) (4)	11 Nov 2020 04:13:44
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 17:17:14
User entered 'colon nodules'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '04 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	10 Nov 2020 21:04:25
User entered '04 Oct 2020'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:16:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 15:32:12 09 Nov 2020 17:16:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Grade 4 (Grade 4)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '1'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Applicable (NOT APPLICABLE)'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '1'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:32:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:16:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide signs and symptoms for the events. If none please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:36:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:32:44
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:32:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:17:27
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 17:17:27
User entered 'Patient was referred to oncologist' reason for change: Data Entry Error	Dhwani Shah (b) (4)	09 Nov 2020 17:17:27
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:16:57
User entered empty.	Dhwani Shah (b) (4)	09 Nov 2020 17:16:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:16:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:36:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:16:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:39:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 21:39:48
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 21:38:51
User entered 'shingles'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '17 Sep 2020'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '07 Oct 2020'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'None (NONE)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 21:38:46
User entered '1' reason for change: Data Entry Error	Dhwani Shah (b) (4)	16 Nov 2020 21:38:46
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 21:38:41
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:27:14
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 21:38:41
	(b) (4)	

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 21:38:41

US3562157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:36:04

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 21:38:41

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:36:04

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:28:06
User closed query 'Per CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	06 Nov 2020 04:19:39
' (Site from DM). Query 'Per CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	Dhwani Shah (b) (4) (b) (4)	04 Nov 2020 23:49:59
' answered with 'con med line 8 and 9 ' (Site from DM). User opened query 'Per CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:12:22
' (Site from DM).		

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:36:04

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Diary Dose 1 (1), Temperature day Log Lines 2,6,7,8 and 9, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:11:46
User opened query 'Per CDM: Diary Dose 1 (1), Temperature day Log Lines 2,6,7,8 and 9, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:11:39
' (Site from DM).		
Query 'er CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:11:08
' canceled (Site from DM).		
User opened query 'er CDM: Diary Dose 2 (1), Temperature day Log Line 3, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.	(b) (4), (b) (6)	03 Nov 2020 07:10:54
' (Site from DM).		
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:53:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: FOSAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 21:56:32
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 Sep 2020 21:56:32
Data point term sent to Coder	System	13 Sep 2020 21:55:12
User entered 'fosamax'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:54:14

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'osteoporosis'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '70'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'every week (QS)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:14
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:54:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:54:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	13 Sep 2020 21:54:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:56:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:56:32
Data point term sent to Coder	System	13 Sep 2020 21:55:12
User entered 'vitamin D3'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'osteoporosis'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '4000'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'IU (IU)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:54:55
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 21:54:55

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 17:44:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 17:44:30
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 17:44:01
Coding entries removed.	Dhwani Shah (b) (4)	15 Oct 2020 17:43:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Sep 2020 05:06:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Sep 2020 05:06:44
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:56:12
User entered 'folic acid'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:32:30
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:43:47
User entered 'FOLIC ACID deficiency' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	15 Oct 2020 17:43:40
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 03:02:39
User entered 'folic acid'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '400'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:55:44
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 21:55:44

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:55:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:55:44
Data point term sent to Coder	System	13 Sep 2020 21:57:13
User entered 'meltonin'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'insominia'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '5'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2008'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:56:17
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 21:56:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:58:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:58:32
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:57:13
User entered 'lexapro'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'insomnia'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '20'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2008'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:10
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 21:57:10

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 06:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 06:16:41
Data point term sent to Coder Coding entries removed.	System Dhwani Shah (b) (4) (b) (4)	26 Sep 2020 17:45:49 26 Sep 2020 17:44:57
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 11:25:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 11:25:41
Data point term sent to Coder User entered 'estradiol cream'	System Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:58:13 13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 17:44:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 17:44:57
User entered 'post menopause syndrome' reason for change: Data Entry Error	Dhwani Shah (b) (4)	26 Sep 2020 17:44:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Sep 2020 21:57:58
	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '10'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'ug (ug)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'other (OTHER)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '2 times a week'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Topical (TOPICAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2019'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:57:58
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:57:58

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:59:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 21:59:32
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 21:59:14
User entered 'sumatriptan'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'migraine'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '100'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'as needed (PRN)'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'un UNK 2015'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	13 Sep 2020 21:58:37
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 21:58:37

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:45:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:45:49
	(b) (4)	
Data point term sent to Coder	System	26 Sep 2020 17:44:49
User entered 'tylenol'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'headache'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '325'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'twice daily (BID)'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '12 Sep 2020'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '12 Sep 2020'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	26 Sep 2020 17:44:39
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 17:44:39

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:24:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:24:44
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 21:23:37
User entered 'tylenol'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'injection site pain'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '650'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'once (ONCE)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '23 Oct 2020'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '23 Oct 2020'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	29 Oct 2020 21:22:52
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:22:52

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:27:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 22:27:54
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 22:26:44
User entered 'ACYCLOVIR'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'SHINGLES'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '800'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'other (OTHER)'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'FIVE TIMES A DAY'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '28 Sep 2020'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '07 Oct 2020'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:26:02
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:26:02

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:02:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	17 Nov 2020 07:02:53
Data point term sent to Coder	System	16 Nov 2020 22:29:47
User entered 'PROGESTERONE CAPS'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'POST Menopause syndrome'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '100'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'mg (mg)'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'once daily (QD)'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '14 Sep 2020'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:28:48
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 22:28:48

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:11:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:11:54
	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 22:30:50
User entered 'lidocaine 2% Cream'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'shingles'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '1'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Other (OTHER)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'applicator'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'as needed (PRN)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'Topical (TOPICAL)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered empty.	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '30 Sep 2020'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '0'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered '05 Oct 2020'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Please update ConMed eCRF with additional ConMeds noted in source: Influenza Vaccine, 30OCT2020, Inj., IM, Flu Prophylaxis. Vitamin B12, start = UNK2019, 5000mcg, PO, QD, nutritional supplement. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:17:02
Query 'Please update ConMed eCRF with additional ConMeds noted in source: Influenza Vaccine, 30OCT2020, Inj., IM, Flu Prophylaxis. Vitamin B12, start = UNK2019, 5000mcg, PO, QD, nutritional supplement. ' answered with 'updated' (Site from CRA).	Dhwani Shah (b) (4)	20 Nov 2020 17:26:47
User opened query 'Please update ConMed eCRF with additional ConMeds noted in source: Influenza Vaccine, 30OCT2020, Inj., IM, Flu Prophylaxis. Vitamin B12, start = UNK2019, 5000mcg, PO, QD, nutritional supplement. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:38:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:36:08
User entered 'No (N)'	Dhwani Shah (b) (4)	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 22:30:06

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 17:29:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 17:29:00
Data point term sent to Coder	System	20 Nov 2020 17:27:57
User entered 'tylenol'	Dhwani Shah (b) (4)	20 Nov 2020 17:27:31
	(b) (4)	

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
User entered 'injection site'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '650'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:27:31

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 17:30:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 17:30:07
Data point term sent to Coder	System	20 Nov 2020 17:28:58
User entered 'influenza vaccine'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
User entered 'flu prophylaxis'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'injection'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:28:17

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 17:46:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 17:46:01
Data point term sent to Coder	System	20 Nov 2020 17:28:58
User entered 'vitamin B12'	Dhwani Shah (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Indication](#)

Audit	User	Time (GMT)
User entered 'nutritional supplement'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5000'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:36:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 17:28:56

US3562157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:36:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User opened query 'Please confirm response. This page will need to be updated with procedures related to subject's cancer diagnosis upon receipt of medical records. Please ensure that all procedures are documented on Concomitant Procedures eCRF. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:40:20
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	13 Sep 2020 21:53:08

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:36:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
User entered '06/Nov/2020 22:58'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:36:04

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)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered		06 Nov 2020 22:57:56
'USA-US071-2020-MRNA-1273-P301000002'	System	

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address:](#) Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:36:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
User entered '10/Nov/2020 14:25'	System	10 Nov 2020 14:25:40

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:36:04

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)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:56:29
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 14:25:40

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered		06 Nov 2020 22:57:56
'USA-US071-2020-MRNA-1273-P301000002'	System	

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:36:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
User entered '11/Nov/2020 19:56'	System	11 Nov 2020 19:56:42

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:36:04

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)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:53:13
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 19:56:42

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'USA-US071-2020-MRNA-1273-P301000002'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'No (N)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Yes (Y)'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Joseph'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Davis'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address:](#) Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '3900 E Camel Back road'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered 'Phoenix'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 22:58:37
User entered '85018'	System	06 Nov 2020 22:57:56

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:25:23
User entered 'US'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:36:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 15:53:33
User entered '3'	System	11 Nov 2020 19:56:42
User entered '2'	System	10 Nov 2020 14:25:40
User entered '1'	System	06 Nov 2020 22:58:43

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:36:04

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:22:06
User entered '12/Nov/2020 15:53'	System	12 Nov 2020 15:53:33

US3562157

Folder: SAE USA-US071-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:36:04

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)	18 Nov 2020 17:22:06
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 15:53:33