

US3632127 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:08:07

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US3632127

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:07

[Participant ID](#)

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

US3632127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:07

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

Condition	GEODON ALLERGY (ANAPHYLAXIS)
Start date (dd MMM yyyy)	1 UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

Condition	HYPERTENSION
Start date (dd MMM yyyy)	1 UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	1 UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

Condition	RHEUMATOID ARTHRITIS (BOTH ANKLES)
Start date (dd MMM yyyy)	1 UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

Condition	HERPES SIMPLEX VIRUS
Start date (dd MMM yyyy)	1 UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

Condition	SMALL BOWEL SURGERY
Start date (dd MMM yyyy)	1 UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	1 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

Condition	SMALL BOWEL REPAIR DUE TO BLOCKAGE
Start date (dd MMM yyyy)	1 UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	1 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

Condition	CONSTIPATION
Start date (dd MMM yyyy)	1 UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	1 UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

Condition	SEVERE OBESITY (BMI 42.13479)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:09
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	248.8 lb
BMI (<i>xxx.x</i>)	42.13479 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 11:08:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 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 11:08:07

Date of assessment (*dd MMM yyyy*) 13 OCT 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 01 UNK 2006

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐
	No ☒
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☒
	No ☐
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☒
	No ☐

Specify

HOME HEALTHCARE WORKER

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 11:08:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

What was the date of randomization? (dd MMM yyyy) 13 OCT 2020

What was the participant's randomization number? 146895

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 11:08:07

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:09
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:40
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	13 OCT 2020
What was the treatment time? (00:00-23:59)	14:10 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 14:10
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

13 OCT 2020

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

12:59 (24 HR)

Collection date and time (derived)

13 OCT 2020 12:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (<i>dd MMM yyyy</i>)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:06	13 OCT 2020 13:06
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 13 OCT 2020 14:41

PC Open Date & Time 13 OCT 2020 14:30

PC Close Date & Time 13 OCT 2020 17:00

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.3 °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):

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

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

PC Time Stamp 13 OCT 2020 19:37

PC Open Date & Time 13 OCT 2020 17:55

PC Close Date & Time 14 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 18:59

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 18:13

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 19:03

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 18:20

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

18 OCT 2020 18:10

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 18:20

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 14:42

PC Open Date & Time

13 OCT 2020 14:30

PC Close Date & Time

13 OCT 2020 17:00

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 19:38

PC Open Date & Time

13 OCT 2020 17:55

PC Close Date & Time

14 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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 OCT 2020 19:00

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 18:13

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 19:03

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 18:21

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 18:11

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 18:21

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 14:43
PC Open Date & Time	13 OCT 2020 14:30
PC Close Date & Time	13 OCT 2020 17:00

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 19:39
PC Open Date & Time	13 OCT 2020 17:55
PC Close Date & Time	14 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	14 OCT 2020 19:00
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	15 OCT 2020 18:14
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	16 OCT 2020 19:04
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	19 OCT 2020 18:21
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 OCT 2020 14:20

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3632127

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 OCT 2020 14:20
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3632127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

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	VISIT2

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 08:15
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 10:31
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3632127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

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.

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to ☐
	Adverse Event ☐
	Physician withheld dose due to ☐
	Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by ☐
	Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	11 NOV 2020
What was the treatment time? (00:00-23:59)	09:51 (24 HR)
Treatment Date and Time (derived)	11 NOV 2020 09:51
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

US3632127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 NOV 2020
Collection time (<i>00:00-23:59</i>)	08:55 (24 HR)
Collection date and time (derived)	11 NOV 2020 08:55

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (<i>dd MMM yyyy</i>)			11 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:01	11 NOV 2020 09:01
Nasopharyngeal Swab 2	No		

US3632127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 NOV 2020 10:29

PC Open Date & Time

11 NOV 2020 10:11

PC Close Date & Time

11 NOV 2020 12:41

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	11 NOV 2020 19:59
PC Open Date & Time	11 NOV 2020 13:36
PC Close Date & Time	12 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 NOV 2020 15:05

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 13 NOV 2020 16:04

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 NOV 2020 13:50

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 NOV 2020 14:30

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 NOV 2020 14:51

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 12:05

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 10:30

PC Open Date & Time

11 NOV 2020 10:11

PC Close Date & Time

11 NOV 2020 12:41

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 20:00

PC Open Date & Time

11 NOV 2020 13:36

PC Close Date & Time

12 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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 NOV 2020 15:08

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 NOV 2020 16:04

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 NOV 2020 13:51

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 14:31

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 14:52

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 12:06

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

PC Time stamp	11 NOV 2020 10:31
PC Open Date & Time	11 NOV 2020 10:11
PC Close Date & Time	11 NOV 2020 12:41

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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

No ☒

Yes ☐

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

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	12 NOV 2020 15:09
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	13 NOV 2020 16:05
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	14 NOV 2020 13:51
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	15 NOV 2020 14:32
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	16 NOV 2020 14:52
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

Yes ☐	
PC Time stamp	17 NOV 2020 12:06
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3632127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted?

Yes ☒

No ☐

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

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

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01 MAR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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10 FEB 2022 00:01

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14 FEB 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 11:08:07

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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

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14 MAR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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21 MAR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

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07 APR 2022 00:01

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11 APR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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26 MAY 2022 00:01

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30 MAY 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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06 JUN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

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08 AUG 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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11 AUG 2022 00:01

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15 AUG 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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18 AUG 2022 00:01

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22 AUG 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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25 AUG 2022 00:01

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29 AUG 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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05 SEP 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

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12 SEP 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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19 SEP 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

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26 SEP 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

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10 OCT 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

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17 OCT 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2022 23:59

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2022 23:59

US3632127

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:08:07

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3632127

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:08:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3632127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

AEID	USA-US120-2020-MRNA-1273-P30 1000004
Adverse event	SEXUAL ASSAULT
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)	07 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)	7 NOV 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	True
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)	331 of 2006

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	PARTICIPANT WAS A VICTIM OF SEXUAL ASSAULT.
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)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

AEID	
Adverse event	FRACTURED, 4TH, RIGHT TOE.
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)	7 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

333 of 2006

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	FRACTURE OCCURED DURING THE SEXUAL ASSAULT
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)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:07

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	LISINOPRIL HCTZ
Prophylaxis	Yes ☐ No ☒
Indication	HYPTERTENSION
Dose per administration	10/12.5
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	1 UNK 2010
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	FISH OILS
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	360
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	1 UNK 2010
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	TURMERIC
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	538
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	NAPROXEN ORAL SUSPENSION
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	1.25/5
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	POWER C GUMMIES
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	GUMMIES
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		1 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	CRANBERRY
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	4200
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	POTASSIUM
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MEQ
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		1 APR 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	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	MAGNESIUM
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		1 APR 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	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	PROBIOTIC
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 UNK 2015
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	APPLE CIDER VINEGAR
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	480
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	ELDERBERRY
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	1250
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		1 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	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	PRAVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	SLIGHTLY ELEVATED CHOLESTEROL
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	VITAMIN D3
Prophylaxis	Yes ☐ No ☒
Indication	TO HELP WITH BONE HEALTH
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

Name of Medication VOLTAREN GEL (DICLOFENAC SODIUM 1% GEL)

Prophylaxis Yes ☐ No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 2

Dose unit mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐

If dose unit is Other, specify

Frequency once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐

If frequency is Other, specify

Route of administration Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 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	☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	CEFTRIAXONE
Prophylaxis	Yes ☐ No ☒
Indication	SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S
Dose per administration	250
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

	Intraocular	☐
	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	ZITHROMAX
Prophylaxis	Yes ☒ No ☐
Indication	SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	FLAGYL
Prophylaxis	Yes ☐ No ☒
Indication	SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	TIVICAY (DOLUTEGRAVIR)
Prophylaxis	Yes ☒ No ☐
Indication	SEXUAL ASSAULT (AE #1)
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		12 NOV 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	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	EMTRICITABINE AND TENOFIVIR DISOPROXIL FUMARATE
Prophylaxis	Yes ☒ No ☐
Indication	SEXUAL ASSAULT
Dose per administration	200/300
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 ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 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	☒

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	FRACTURED TOE (AE)
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		7 NOV 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	☒

US3632127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:07

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3632127

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:07

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3632127

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:07

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US120-2020-MRNA-1273-P301000004
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US120-2020-MRNA-1273-P301000004
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:57
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

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US120-2020-MRNA-1273-P301000004
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:58
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

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:08:07

SAEID	USA-US120-2020-MRNA-1273-P301000004
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:42
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

US3632127 (Prod: Grady Health System)

US3632127

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:07

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3632127'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Oct 2020 15:33:31

US3632127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:57:47

US3632127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Oct 2020 15:33:33

US3632127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:57:47

US3632127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	13 Oct 2020 17:57:47

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Oct 2020 15:33:34

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Age](#)

Audit	User	Time (GMT)
User entered '57'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '57'	System	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[White](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:07

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:15

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:31

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Oct 2020 15:33:33

US3632127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 17:58:39

US3632127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:07

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:39

US3632127

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:58:48

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:03:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:03:21
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Geodon Allergy (anaphylaxis)'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 1993'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1993'	System	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:47:28

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:49:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:49:23
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Hypertension'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2010'	System	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:47:39

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:49:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:49:23
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Osteoarthritis'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2003'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2003'	System	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:47:51

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:23:11
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Participant takes Vitamin D3 for bone health and uses Voltaren Gel as needed on your ankles. Medications are being adding to the conmed.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:09:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:44:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:23:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:23:22
Data point term sent to Coder	System	13 Oct 2020 20:48:27
User entered 'Rheumatoid Arthritis (both ankles)'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2016'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2016'	System	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:48:12

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:50:16
Data point term sent to Coder	System	13 Oct 2020 20:49:28
User entered 'Herpes Simplex Virus'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2012'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:26:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:26:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:26:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:48:46
User entered empty.	(b) (4), (b) (6) (b) (4)	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2012'	System	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:48:46

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestine operation, LLT: Small intestine operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:19:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:19:26
Data point term sent to Coder	System	13 Oct 2020 20:49:33
User entered 'Small Bowel Surgery'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 1994'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	14 Oct 2020 12:32:09
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:32:09
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	13 Oct 2020 20:49:08
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 1994'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1994'	System	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1994'	System	13 Oct 2020 20:49:08

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestinal resection, LLT: Small bowel resection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 12:53:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 12:53:30
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:41:28
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Participant believes this was due to blockage, participant was not sure of the reason or condition that led to procedure. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:09:13
Data point term sent to Coder	System	03 Nov 2020 16:08:52
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 16:08:44
User entered 'SMALL BOWEL REPAIR due to blockage' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 16:08:44
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:47:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Small intestine operation, LLT: Small intestine operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:21:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:21:23
Data point term sent to Coder	System	13 Oct 2020 20:49:34
User entered 'Small Bowel Repair'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2013'	System	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2013'	System	13 Oct 2020 20:49:30

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:51:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:51:19
Data point term sent to Coder	System	13 Oct 2020 20:50:37
User entered 'Constipation'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 1994'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1994'	System	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:49:42

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
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 Oct 2020 20:51:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 20:51:20
Data point term sent to Coder	System	13 Oct 2020 20:50:39
User entered 'Post Menopausal'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 UNK 2006'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2006'	System	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:50:01

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:22:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:22:24
Data point term sent to Coder	System	23 Oct 2020 18:54:02
User entered 'SEVERE OBESITY (BMI 42.13479)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:53:38
User entered 'Severe Obesity'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:08:07

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:53:25

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:09'	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:09'	System	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '64.5' in	(b) (4), (b) (6)	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '248.8' lb	(b) (4), (b) (6)	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

BMI (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:50:22
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'Medical Hx updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:53:09
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 19:36:07
User entered '42.13479'	System	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	13 Oct 2020 20:43:47
DataPoint set to visible.	System	13 Oct 2020 17:58:39

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:43:47

US3632127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:05

US3632127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:05

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 UNK 2006'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:07

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 17:59:30

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 18:01:24
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:01:03
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Specify](#)

Audit	User	Time (GMT)
User entered 'Home Healthcare Worker'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:07

[Specify](#)

Audit	User	Time (GMT)
User entered 'Multi room residential home'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:03

US3632127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:15:02

US3632127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:15:02

US3632127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:15:02

US3632127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Oct 2020 18:15:02

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	13 Oct 2020 17:03:44

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '146895'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Oct 2020 17:03:44

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	13 Oct 2020 17:03:44

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:18:48
User entered 'Yes (Y)'	Kelly Likos (b) (4)	13 Oct 2020 18:01:46

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:01:46

US3632127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:07

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4)	13 Oct 2020 18:01:46
DataPoint set to visible.	(b) (4) System	13 Oct 2020 17:58:31

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:09'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:09'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '87'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:07

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:40'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:40'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	(b) (4), (b) (6)	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:46:24

US3632127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:02:17

US3632127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:02:17

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:10'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:10'	System	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 18:14:30

US3632127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:03

US3632127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:03

US3632127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:59'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:03

US3632127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:59'	System	13 Oct 2020 18:17:03

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '13:06'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:06'	System	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:17:21

US3632127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kelly Likos (b) (4) (b) (4)	13 Oct 2020 18:18:09

US3632127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 18:18:09

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:24', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427'	System	13 Oct 2020 18:41:50
User entered 'Yes (Y)'	System	13 Oct 2020 18:41:50

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427'	System	13 Oct 2020 18:41:50
User entered '98.7'	System	13 Oct 2020 18:41:50

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427'	System	13 Oct 2020 18:41:50
User entered 'No (N)'	System	13 Oct 2020 18:41:50

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:41:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'db35cadc-a595-4922-b1fc-a0ecff557427'	System	13 Oct 2020 18:41:50
User entered '13 Oct 2020 14:41'	System	13 Oct 2020 18:41:50

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:30'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:35:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb'	System	13 Oct 2020 23:37:24
User entered 'Yes (Y)'	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:36:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered '99.3'	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb'	System	13 Oct 2020 23:37:24
User entered 'Yes (Y)'	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

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 'was contacted and eCRFs has been updated' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 07:23:21
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 (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered '1'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:16:13
	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb' User entered '0'	System	13 Oct 2020 23:37:24
	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '78dbd2ec-3055-4f99-8fab-9a0fd58c3bbb'	System	13 Oct 2020 23:37:24
User entered '13 Oct 2020 19:37'	System	13 Oct 2020 23:37:24

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:55'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 2'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9'	System	14 Oct 2020 22:59:43
User entered 'Yes (Y)'	System	14 Oct 2020 22:59:43

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:26', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9'	System	14 Oct 2020 22:59:43
User entered '98.5'	System	14 Oct 2020 22:59:43

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9'	System	14 Oct 2020 22:59:43
User entered 'No (N)'	System	14 Oct 2020 22:59:43

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8882121f-0f49-4315-a102-9a018c027de9'	System	14 Oct 2020 22:59:43
User entered '14 Oct 2020 18:59'	System	14 Oct 2020 22:59:43

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 3'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:12:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5'	System	15 Oct 2020 22:13:11
User entered 'Yes (Y)'	System	15 Oct 2020 22:13:11

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5'	System	15 Oct 2020 22:13:11
User entered '97.5'	System	15 Oct 2020 22:13:11

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5'	System	15 Oct 2020 22:13:11
User entered 'No (N)'	System	15 Oct 2020 22:13:11

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a21844ba-dcc3-483e-bcc9-dbd1dd09a5f5'	System	15 Oct 2020 22:13:11
User entered '15 Oct 2020 18:13'	System	15 Oct 2020 22:13:11

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 4'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:02:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f'	System	16 Oct 2020 23:03:26
User entered 'Yes (Y)'	System	16 Oct 2020 23:03:26

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f'	System	16 Oct 2020 23:03:26
User entered '98.4'	System	16 Oct 2020 23:03:26

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f'	System	16 Oct 2020 23:03:26
User entered 'No (N)'	System	16 Oct 2020 23:03:26

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8956e9fa-eb03-4509-a0e1-43f8f155fe9f'	System	16 Oct 2020 23:03:26
User entered '16 Oct 2020 19:03'	System	16 Oct 2020 23:03:26

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 5'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:19:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77'	System	17 Oct 2020 22:20:27
User entered 'Yes (Y)'	System	17 Oct 2020 22:20:27

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77'	System	17 Oct 2020 22:20:27
User entered '99.1'	System	17 Oct 2020 22:20:27

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77'	System	17 Oct 2020 22:20:27
User entered 'No (N)'	System	17 Oct 2020 22:20:27

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac8ad103-2938-444e-b3bd-4d0ced4f9f77'	System	17 Oct 2020 22:20:27
User entered '17 Oct 2020 18:20'	System	17 Oct 2020 22:20:27

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 6'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75'	System	18 Oct 2020 22:10:51
User entered 'Yes (Y)'	System	18 Oct 2020 22:10:51

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75'	System	18 Oct 2020 22:10:51
User entered '99.2'	System	18 Oct 2020 22:10:51

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75'	System	18 Oct 2020 22:10:51
User entered 'No (N)'	System	18 Oct 2020 22:10:51

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e28ba8c6-3c08-4a11-bcd5-cd565e536f75'	System	18 Oct 2020 22:10:51
User entered '18 Oct 2020 18:10'	System	18 Oct 2020 22:10:51

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 7'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:19:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered 'Yes (Y)'	System	19 Oct 2020 22:21:00

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:20:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered '98.1'	System	19 Oct 2020 22:21:00

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:20:53', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered 'No (N)'	System	19 Oct 2020 22:21:00

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:20:56', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9f0b0fa-af25-4f7b-8001-9c7f3758aa97'	System	19 Oct 2020 22:21:00
User entered '19 Oct 2020 18:20'	System	19 Oct 2020 22:21:00

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered 'None (1)'	System	13 Oct 2020 18:42:47

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered 'No (N)'	System	13 Oct 2020 18:42:47

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered 'No (N)'	System	13 Oct 2020 18:42:47

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered 'None (1)'	System	13 Oct 2020 18:42:47

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8a0fdd7f-3545-4391-8f2a-ebec1263a7a3'	System	13 Oct 2020 18:42:47
User entered '13 Oct 2020 14:42'	System	13 Oct 2020 18:42:47

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:30'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'None (1)'	System	13 Oct 2020 23:38:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'No (N)'	System	13 Oct 2020 23:38:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:37:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'No (N)'	System	13 Oct 2020 23:38:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered 'None (1)'	System	13 Oct 2020 23:38:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '593cab0f-aa92-4da5-9962-5107c441b7a6'	System	13 Oct 2020 23:38:08
User entered '13 Oct 2020 19:38'	System	13 Oct 2020 23:38:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:55'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 2'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106'	System	14 Oct 2020 23:00:08
User entered 'None (1)'	System	14 Oct 2020 23:00:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:50', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106'	System	14 Oct 2020 23:00:08
User entered 'No (N)'	System	14 Oct 2020 23:00:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T18:59:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106'	System	14 Oct 2020 23:00:08
User entered 'No (N)'	System	14 Oct 2020 23:00:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106'	System	14 Oct 2020 23:00:08
User entered 'None (1)'	System	14 Oct 2020 23:00:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '516e9c2a-0632-4ac9-968d-471329e04106'	System	14 Oct 2020 23:00:08
User entered '14 Oct 2020 19:00'	System	14 Oct 2020 23:00:08

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 3'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'None (1)'	System	15 Oct 2020 22:13:37

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'No (N)'	System	15 Oct 2020 22:13:37

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'No (N)'	System	15 Oct 2020 22:13:37

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered 'None (1)'	System	15 Oct 2020 22:13:37

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8c43d413-aa76-4c71-b84d-0db1381b8b44'	System	15 Oct 2020 22:13:37
User entered '15 Oct 2020 18:13'	System	15 Oct 2020 22:13:37

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 4'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'None (1)'	System	16 Oct 2020 23:03:48

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'No (N)'	System	16 Oct 2020 23:03:48

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'No (N)'	System	16 Oct 2020 23:03:48

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered 'None (1)'	System	16 Oct 2020 23:03:48

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '785ab381-c5da-4e66-adab-769a31973459'	System	16 Oct 2020 23:03:48
User entered '16 Oct 2020 19:03'	System	16 Oct 2020 23:03:48

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 5'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d'	System	17 Oct 2020 22:21:35
User entered 'None (1)'	System	17 Oct 2020 22:21:35

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:20:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d'	System	17 Oct 2020 22:21:35
User entered 'No (N)'	System	17 Oct 2020 22:21:35

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:00', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d'	System	17 Oct 2020 22:21:35
User entered 'No (N)'	System	17 Oct 2020 22:21:35

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d'	System	17 Oct 2020 22:21:35
User entered 'None (1)'	System	17 Oct 2020 22:21:35

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3e82052a-e29e-47f3-b811-52e0b2f3c57d' User entered '17 Oct 2020 18:21'	System	17 Oct 2020 22:21:35
	System	17 Oct 2020 22:21:35

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 6'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:10:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'None (1)'	System	18 Oct 2020 22:11:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'No (N)'	System	18 Oct 2020 22:11:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'No (N)'	System	18 Oct 2020 22:11:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3'	System	18 Oct 2020 22:11:30
User entered 'None (1)'	System	18 Oct 2020 22:11:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a72e4769-d95c-4c43-af90-afe615edaac3' User entered '18 Oct 2020 18:11'	System	18 Oct 2020 22:11:30
	System	18 Oct 2020 22:11:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 7'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered 'None (1)'	System	19 Oct 2020 22:21:18

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:03', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered 'No (N)'	System	19 Oct 2020 22:21:18

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered 'No (N)'	System	19 Oct 2020 22:21:18

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:11', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered 'None (1)'	System	19 Oct 2020 22:21:18

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7ec7591d-d917-44b3-8cc7-d0ea914a26d3'	System	19 Oct 2020 22:21:18
User entered '19 Oct 2020 18:21'	System	19 Oct 2020 22:21:18

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0'	System	13 Oct 2020 18:43:19
User entered 'None (0)'	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered 'None (0)'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:42:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0'	System	13 Oct 2020 18:43:19
User entered 'None (0)'	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0'	System	13 Oct 2020 18:43:19
User entered 'None (0)'	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0'	System	13 Oct 2020 18:43:19
User entered 'None (0)'	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0'	System	13 Oct 2020 18:43:19
User entered 'None (0)'	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0'	System	13 Oct 2020 18:43:19
User entered 'No (N)'	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T14:43:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '63290041-5a85-4e6e-8132-7bad7f7695e0' User entered '13 Oct 2020 14:43'	System	13 Oct 2020 18:43:19
	System	13 Oct 2020 18:43:19

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:30'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No interference with activity (1)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'None (0)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No interference with activity (1)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No interference with activity (1)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'None (0)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:38:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'None (0)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:39:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered 'No (N)'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-13T19:39:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7789e156-d355-4068-aeeb-ba09aa23eaa7'	System	13 Oct 2020 23:39:13
User entered '13 Oct 2020 19:39'	System	13 Oct 2020 23:39:13

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:55'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 2'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'None (0)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'None (0)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'None (0)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'None (0)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'None (0)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'None (0)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered 'No (N)'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-14T19:00:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7cc3697d-cad0-423b-8f07-e5e82a6851c1'	System	14 Oct 2020 23:00:40
User entered '14 Oct 2020 19:00'	System	14 Oct 2020 23:00:40

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 3'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'None (0)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'None (0)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:13:54', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'None (0)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'None (0)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'None (0)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'None (0)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered 'No (N)'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-15T18:14:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b93e6581-51b8-4800-ba8f-15d08c0440b8'	System	15 Oct 2020 22:14:28
User entered '15 Oct 2020 18:14'	System	15 Oct 2020 22:14:28

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 4'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'None (0)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'None (0)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:03:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'None (0)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'None (0)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'None (0)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'None (0)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered 'No (N)'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-16T19:04:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '90b4e129-fd40-409a-a184-46364b25fe51'	System	16 Oct 2020 23:04:23
User entered '16 Oct 2020 19:04'	System	16 Oct 2020 23:04:23

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 5'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f'	System	17 Oct 2020 22:22:05
User entered 'None (0)'	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f'	System	17 Oct 2020 22:22:05
User entered 'None (0)'	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f'	System	17 Oct 2020 22:22:05
User entered 'None (0)'	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:45', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered 'None (0)'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f'	System	17 Oct 2020 22:22:05
User entered 'None (0)'	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f'	System	17 Oct 2020 22:22:05
User entered 'None (0)'	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f'	System	17 Oct 2020 22:22:05
User entered 'No (N)'	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-17T18:21:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '4ac760b3-e8a5-4f75-9a74-a0c3474ff47f' User entered '17 Oct 2020 18:21'	System	17 Oct 2020 22:22:05
	System	17 Oct 2020 22:22:05

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 6'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee'	System	18 Oct 2020 22:12:11
User entered 'None (0)'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee'	System	18 Oct 2020 22:12:11
User entered 'None (0)'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee'	System	18 Oct 2020 22:12:11
User entered 'No interference with activity (1)'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee'	System	18 Oct 2020 22:12:11
User entered 'No interference with activity (1)'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered 'None (0)'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:11:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee'	System	18 Oct 2020 22:12:11
User entered 'None (0)'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:12:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee'	System	18 Oct 2020 22:12:11
User entered 'No (N)'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-18T18:12:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'd0600627-3645-4b6f-9297-034c8036c7ee' User entered '18 Oct 2020 18:12'	System	18 Oct 2020 22:12:11
	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 18:14:30
User entered 'Day 7'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'None (0)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'None (0)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'No interference with activity (1)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'None (0)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'None (0)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'None (0)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered 'No (N)'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-19T18:21:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0f246fa8-a542-443c-b2d4-294c15dc5f75'	System	19 Oct 2020 22:21:48
User entered '19 Oct 2020 18:21'	System	19 Oct 2020 22:21:48

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 18:14:30

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 22:12:11
User entered 'Day 8'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:08:07

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:19:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8781dc80-270f-4334-87a6-304e5c481a1f'	System	20 Oct 2020 18:20:07
User entered 'None (0)'	System	20 Oct 2020 18:20:07

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:20:03', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8781dc80-270f-4334-87a6-304e5c481a1f' User entered '20 Oct 2020 14:20'	System	20 Oct 2020 18:20:07
	System	20 Oct 2020 18:20:07

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 22:12:11
User entered 'Day 8'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:20:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6b34973b-9b8e-499e-8457-c9476778860a'	System	20 Oct 2020 18:20:14
User entered 'No (N)'	System	20 Oct 2020 18:20:14

US3632127

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-10-20T14:20:13', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '6b34973b-9b8e-499e-8457-c9476778860a'	System	20 Oct 2020 18:20:14
User entered '20 Oct 2020 14:20'	System	20 Oct 2020 18:20:14

US3632127

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 22:12:11

US3632127

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 22:12:11

US3632127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	20 Oct 2020 15:12:48
	(b) (4)	

US3632127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Bezuayehu Mandefro	20 Oct 2020 15:12:48
	(b) (4)	

US3632127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Bezuayehu Mandefro (b) (4) 	20 Oct 2020 15:12:48

US3632127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Bezuayehu Mandefro	20 Oct 2020 15:12:48
	(b) (4)	

US3632127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bezuayehu Mandefro	20 Oct 2020 15:12:53
	(b) (4)	

US3632127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 15:12:53

US3632127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 18:00:29

US3632127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 18:00:33

US3632127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 18:00:33

US3632127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:06:11

US3632127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:06:02

US3632127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 16:06:02

US3632127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:25

US3632127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:25

US3632127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:25

US3632127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	11 Nov 2020 14:21:25

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:15'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 08:15'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '114'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:31'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 10:31'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '20'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '110'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 16:08:34

US3632127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:33

US3632127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:33

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:51'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 09:51'	System	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Nov 2020 14:55:46

US3632127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:44

US3632127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:44

US3632127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:55'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:44

US3632127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 08:55'	System	11 Nov 2020 14:21:44

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Wiatrek (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '09:01'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 09:01'	System	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Wiatrek (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:21:58

US3632127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	11 Nov 2020 16:08:41

US3632127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:08:41

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6'	System	11 Nov 2020 15:29:58
User entered 'Yes (Y)'	System	11 Nov 2020 15:29:58

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6'	System	11 Nov 2020 15:29:58
User entered '98.3'	System	11 Nov 2020 15:29:58

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6'	System	11 Nov 2020 15:29:58
User entered 'No (N)'	System	11 Nov 2020 15:29:58

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:29:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ef5619fb-f153-4251-9f2a-ca6b784174e6'	System	11 Nov 2020 15:29:58
User entered '11 Nov 2020 10:29'	System	11 Nov 2020 15:29:58

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 10:11'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:41'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141'	System	12 Nov 2020 00:59:59
User entered 'Yes (Y)'	System	12 Nov 2020 00:59:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141'	System	12 Nov 2020 00:59:59
User entered '98.1'	System	12 Nov 2020 00:59:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141'	System	12 Nov 2020 00:59:59
User entered 'No (N)'	System	12 Nov 2020 00:59:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T19:59:56', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '3eb13b19-d5a8-4905-86c3-7de62e136141'	System	12 Nov 2020 00:59:59
User entered '11 Nov 2020 19:59'	System	12 Nov 2020 00:59:59

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 13:36'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 2'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:04:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa'	System	12 Nov 2020 20:05:53
User entered 'Yes (Y)'	System	12 Nov 2020 20:05:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:05:38', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa'	System	12 Nov 2020 20:05:53
User entered '98.7'	System	12 Nov 2020 20:05:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:05:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa'	System	12 Nov 2020 20:05:53
User entered 'No (N)'	System	12 Nov 2020 20:05:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:05:48', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '59a1e157-9aaf-4107-8bc7-4d04f288a5fa'	System	12 Nov 2020 20:05:53
User entered '12 Nov 2020 15:05'	System	12 Nov 2020 20:05:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 3'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a'	System	13 Nov 2020 21:04:30
User entered 'Yes (Y)'	System	13 Nov 2020 21:04:30

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a'	System	13 Nov 2020 21:04:30
User entered '97.6'	System	13 Nov 2020 21:04:30

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a'	System	13 Nov 2020 21:04:30
User entered 'No (N)'	System	13 Nov 2020 21:04:30

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e77f448b-3a4f-4799-b86c-59bffe53170a'	System	13 Nov 2020 21:04:30
User entered '13 Nov 2020 16:04'	System	13 Nov 2020 21:04:30

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 4'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:49:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered 'Yes (Y)'	System	14 Nov 2020 18:50:25

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:11', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered '97.6'	System	14 Nov 2020 18:50:25

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered 'No (N)'	System	14 Nov 2020 18:50:25

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e9c5a72c-9536-4e5f-befd-9eda2376c466'	System	14 Nov 2020 18:50:25
User entered '14 Nov 2020 13:50'	System	14 Nov 2020 18:50:25

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 5'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4'	System	15 Nov 2020 19:30:52
User entered 'Yes (Y)'	System	15 Nov 2020 19:30:52

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4' User entered '98.1'	System	15 Nov 2020 19:30:52
	System	15 Nov 2020 19:30:52

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4'	System	15 Nov 2020 19:30:52
User entered 'No (N)'	System	15 Nov 2020 19:30:52

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:30:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'e27330d4-d447-4ce1-aaca-d040aeb0b5b4'	System	15 Nov 2020 19:30:52
User entered '15 Nov 2020 14:30'	System	15 Nov 2020 19:30:52

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 6'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:50:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d'	System	16 Nov 2020 19:51:53
User entered 'Yes (Y)'	System	16 Nov 2020 19:51:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d'	System	16 Nov 2020 19:51:53
User entered '98.3'	System	16 Nov 2020 19:51:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d'	System	16 Nov 2020 19:51:53
User entered 'No (N)'	System	16 Nov 2020 19:51:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a9ec7036-b74d-4469-802d-41dafbaf7e2d'	System	16 Nov 2020 19:51:53
User entered '16 Nov 2020 14:51'	System	16 Nov 2020 19:51:53

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 7'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered 'Yes (Y)'	System	17 Nov 2020 17:06:00

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered '98.1'	System	17 Nov 2020 17:06:00

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered 'No (N)'	System	17 Nov 2020 17:06:00

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:05:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'fbd637a7-3ccb-4802-b905-0f3ef3ffdf52'	System	17 Nov 2020 17:06:00
User entered '17 Nov 2020 12:05'	System	17 Nov 2020 17:06:00

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'None (1)'	System	11 Nov 2020 15:30:51

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'No (N)'	System	11 Nov 2020 15:30:51

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'No (N)'	System	11 Nov 2020 15:30:51

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:45', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered 'None (1)'	System	11 Nov 2020 15:30:51

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '8fca385e-1047-4666-88da-c477e32c4187'	System	11 Nov 2020 15:30:51
User entered '11 Nov 2020 10:30'	System	11 Nov 2020 15:30:51

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 10:11'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:41'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1'	System	12 Nov 2020 01:00:15
User entered 'None (1)'	System	12 Nov 2020 01:00:15

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1'	System	12 Nov 2020 01:00:15
User entered 'No (N)'	System	12 Nov 2020 01:00:15

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1'	System	12 Nov 2020 01:00:15
User entered 'No (N)'	System	12 Nov 2020 01:00:15

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1'	System	12 Nov 2020 01:00:15
User entered 'None (1)'	System	12 Nov 2020 01:00:15

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c86f19f7-a542-4d69-9481-d6dd36901cf1'	System	12 Nov 2020 01:00:15
User entered '11 Nov 2020 20:00'	System	12 Nov 2020 01:00:15

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 13:36'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 2'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:06:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481'	System	12 Nov 2020 20:08:10
User entered 'None (1)'	System	12 Nov 2020 20:08:10

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:07:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481'	System	12 Nov 2020 20:08:10
User entered 'No (N)'	System	12 Nov 2020 20:08:10

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:07:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481'	System	12 Nov 2020 20:08:10
User entered 'No (N)'	System	12 Nov 2020 20:08:10

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481'	System	12 Nov 2020 20:08:10
User entered 'None (1)'	System	12 Nov 2020 20:08:10

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7b93190e-e333-4e98-9031-ce4fcb738481'	System	12 Nov 2020 20:08:10
User entered '12 Nov 2020 15:08'	System	12 Nov 2020 20:08:10

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 3'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'None (1)'	System	13 Nov 2020 21:05:45

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:40', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'No (N)'	System	13 Nov 2020 21:05:45

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:44', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'No (N)'	System	13 Nov 2020 21:05:45

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered 'None (1)'	System	13 Nov 2020 21:05:45

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '9c2304e3-0a79-47b9-9cda-2bce4426e821'	System	13 Nov 2020 21:05:45
User entered '13 Nov 2020 16:04'	System	13 Nov 2020 21:05:45

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 4'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:47', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'None (1)'	System	14 Nov 2020 18:51:22

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:50:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'No (N)'	System	14 Nov 2020 18:51:22

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:01', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'No (N)'	System	14 Nov 2020 18:51:22

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered 'None (1)'	System	14 Nov 2020 18:51:22

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '1c6df213-fcfa-43c3-9117-0b3a831bf3d4'	System	14 Nov 2020 18:51:22
User entered '14 Nov 2020 13:51'	System	14 Nov 2020 18:51:22

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 5'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be'	System	15 Nov 2020 19:31:27
User entered 'None (1)'	System	15 Nov 2020 19:31:27

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:06', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be'	System	15 Nov 2020 19:31:27
User entered 'No (N)'	System	15 Nov 2020 19:31:27

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:11', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be'	System	15 Nov 2020 19:31:27
User entered 'No (N)'	System	15 Nov 2020 19:31:27

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be'	System	15 Nov 2020 19:31:27
User entered 'None (1)'	System	15 Nov 2020 19:31:27

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:23', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'a961f60f-ae08-4a1e-af4a-65bb212c18be' User entered '15 Nov 2020 14:31'	System	15 Nov 2020 19:31:27
	System	15 Nov 2020 19:31:27

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 6'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:53', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'None (1)'	System	16 Nov 2020 19:52:16

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:51:58', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'No (N)'	System	16 Nov 2020 19:52:16

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:03', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'No (N)'	System	16 Nov 2020 19:52:16

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered 'None (1)'	System	16 Nov 2020 19:52:16

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:09', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '0e975e5f-8783-4b04-8af3-591fe2cd9459'	System	16 Nov 2020 19:52:16
User entered '16 Nov 2020 14:52'	System	16 Nov 2020 19:52:16

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 7'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:07', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'None (1)'	System	17 Nov 2020 17:06:24

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:10', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'No (N)'	System	17 Nov 2020 17:06:24

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:14', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'No (N)'	System	17 Nov 2020 17:06:24

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:18', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered 'None (1)'	System	17 Nov 2020 17:06:24

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:21', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '7da78623-593a-4450-90c6-477cd6006492'	System	17 Nov 2020 17:06:24
User entered '17 Nov 2020 12:06'	System	17 Nov 2020 17:06:24

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'None (0)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:30:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'None (0)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:02', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'None (0)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'None (0)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:08', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'None (0)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'None (0)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:17', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered 'No (N)'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T10:31:24', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '774a3f3c-0399-4013-b7b5-4925a76b34c7'	System	11 Nov 2020 15:31:26
User entered '11 Nov 2020 10:31'	System	11 Nov 2020 15:31:26

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 10:11'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 12:41'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'None (0)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'None (0)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No interference with activity (1)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:28', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No interference with activity (1)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'None (0)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered 'No (N)'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-11T20:00:43', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'da3123f2-a1bf-48a9-a1f5-9ec521bac54b'	System	12 Nov 2020 01:00:51
User entered '11 Nov 2020 20:00'	System	12 Nov 2020 01:00:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 13:36'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 2'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:13', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:45', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:08:51', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:09:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'None (0)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:09:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered 'No (N)'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-12T15:09:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '32d6e9e0-6c22-4f50-a721-00b0c86faaa4'	System	12 Nov 2020 20:09:40
User entered '12 Nov 2020 15:09'	System	12 Nov 2020 20:09:40

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 3'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:04:59', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'None (0)'	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:05', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'None (0)'	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:12', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'No interference with activity (1)'	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:16', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'No interference with activity (1)'	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'None (0)'	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered 'None (0)'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:31', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0'	System	13 Nov 2020 21:06:01
User entered 'No (N)'	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-13T16:05:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'aea84a8f-9991-49d3-86a1-92e01b9400b0' User entered '13 Nov 2020 16:05'	System	13 Nov 2020 21:06:01
	System	13 Nov 2020 21:06:01

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 4'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:26', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'None (0)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'None (0)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:34', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'None (0)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'None (0)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'None (0)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'None (0)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:52', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc'	System	14 Nov 2020 18:51:59
User entered 'No (N)'	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-14T13:51:55', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: '07bf9ba7-cde7-4683-ba1c-910fe12176fc' User entered '14 Nov 2020 13:51'	System	14 Nov 2020 18:51:59
	System	14 Nov 2020 18:51:59

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 5'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'None (0)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No interference with activity (1)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:41', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No interference with activity (1)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:53', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No interference with activity (1)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:31:57', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'None (0)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:32:04', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'None (0)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:32:20', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered 'No (N)'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-15T14:32:25', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'b7ba0cca-fefd-4ef7-b27f-0eb7a84a2c07'	System	15 Nov 2020 19:32:29
User entered '15 Nov 2020 14:32'	System	15 Nov 2020 19:32:29

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 6'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:15', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'None (0)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:19', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'None (0)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:22', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'None (0)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:26', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'None (0)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'None (0)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:32', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'None (0)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:35', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f'	System	16 Nov 2020 19:52:44
User entered 'No (N)'	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-16T14:52:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'ac2d8c76-57c9-481c-8c9c-044990f4610f' User entered '16 Nov 2020 14:52'	System	16 Nov 2020 19:52:44
	System	16 Nov 2020 19:52:44

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Nov 2020 14:55:46
User entered 'Day 7'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:27', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'None (0)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:30', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'None (0)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:33', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'None (0)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:36', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'None (0)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:39', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'None (0)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:42', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'None (0)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:46', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered 'No (N)'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3864B53-3C5A-4A57-8E2A-06D4FB0E58E3)', Time: '2020-11-17T12:06:49', User OID: 'PatientReportedOutcome (US3632127)', ODM File OID: 'c594f089-3a05-4fd8-9835-6c54f506e2c5'	System	17 Nov 2020 17:06:51
User entered '17 Nov 2020 12:06'	System	17 Nov 2020 17:06:51

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 14:55:46

US3632127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 14:55:46

US3632127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:49

US3632127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:49

US3632127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:49

US3632127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:49

US3632127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4) (b) (4)	18 Nov 2020 16:46:53

US3632127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:46:53

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '08 Dec 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '12 Dec 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '15 Dec 2022 00:01'	System	20 Nov 2020 12:26:41

US3632127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:26:41
Amendment Manager: User entered '19 Dec 2022 23:59'	System	20 Nov 2020 12:26:41

US3632127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 16:45:37

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:05
User entered 'USA-US120-2020-mRNA-1273-P301000004'	System	11 Nov 2020 20:57:02
User entered 'New'	(b) (4), (b) (6)	11 Nov 2020 20:57:02

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:28
User coded data point as SOC: Social circumstances, HLGT: Legal issues, HLT: Criminal activity, PT: Sexual abuse, LLT: Sexual assault - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 17:02:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Nov 2020 17:02:41
Data point term sent to Coder	System	10 Nov 2020 17:02:11
User entered 'sexual assault'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:43
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:22:59
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 14:01:52
User entered empty; reason for change New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:52
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	
User entered '17:30' reason for change: New Information	System	11 Nov 2020 14:01:24
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:01:52
User entered '07 Nov 2020 17:30'	System	11 Nov 2020 14:01:24
User entered empty.	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:49
User entered 'No (N)' reason for change: New Information	Christina Bacher (b) (4)	13 Nov 2020 15:43:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'Yes (Y)' reason for change: New Information	System	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User entered empty.	(b) (4)	
	System	10 Nov 2020 17:01:41
	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:51
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Nov 2020 15:44:17
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Nov 2020 15:44:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Nov 2020 15:43:54
User entered '7 Nov 2020' reason for change: New Information	Christina Bacher (b) (4)	13 Nov 2020 15:43:54
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:53
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:56
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:19:58
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Nov 2020 14:01:24
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Nov 2020 17:01:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:00
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:02
User entered '1' reason for change: New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:09
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:11
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:14
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:15
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:17
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:20
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:21
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:23
User entered '1' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:27
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:20:58
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'None (NONE)' reason for change: New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:21:48
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:21:49
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:28:27
DataPoint Un-verified.	Catherine Abrams (b) (4)	19 Nov 2020 21:18:58
User entered '0' reason for change: Data Entry Error	(b) (4) Catherine Abrams (b) (4)	19 Nov 2020 21:18:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:21:53
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:22:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Christina Bacher (b) (4)	13 Nov 2020 15:44:17
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:22:47
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Participant was not tested for COVID-19' (Site from Safety).	Christina Bacher (b) (4)	24 Nov 2020 18:45:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'In process of obtaining records' (Site from Safety).	Christina Bacher (b) (4)	24 Nov 2020 18:45:22
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:29:36
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)	20 Nov 2020 16:28:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:22:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 14:01:24
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 14:01:24
User entered 'PARTICIPANT WAS A VICTIM OF SEXUAL ASSAULT.' reason for change: New Information	Christina Bacher (b) (4)	11 Nov 2020 14:01:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 17:01:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 17:01:41

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:16
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Fractured toe - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:33
Data point term sent to Coder	System	11 Nov 2020 14:03:53
User entered 'FRACTURED, 4TH, RIGHT TOE.'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:25
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:27
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:29
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:31
User entered '7 Nov 2020'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:32
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:34
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:37
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:39
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:43
User entered 'No (N)'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:44
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:47
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:49
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12
	(b) (4)	

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:51
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:53
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:54
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:56
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:23:57
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:00
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:03
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:05
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:03:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:12
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:07
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:03:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:12
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:10
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 14:03:43
User entered 'None (NONE)' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:03:43
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 14:03:12
User entered empty.	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 21:35:02
User closed query 'Per source, other actions taken include Medication. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 21:35:00
Query 'Per source, other actions taken include Medication. Please verify with source and update EDC accordingly.' answered with 'Naproxen ' (Site from CRA).	Catherine Abrams (b) (4)	19 Nov 2020 21:14:39
User entered '0' reason for change: Per Query Resolution	Catherine Abrams (b) (4)	19 Nov 2020 21:13:40
User opened query 'Per source, other actions taken include Medication. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 17:24:36
User entered '1'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 21:35:04
User entered '1' reason for change: Per Query Resolution	Catherine Abrams (b) (4)	19 Nov 2020 21:13:40
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:39
User entered '0'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:46
User entered empty.	Christina Bacher (b) (4) (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:24:47
User entered 'FRACTURE OCCURED DURING THE SEXUAL ASSAULT' reason for change: Data Entry Error	Christina Bacher (b) (4)	11 Nov 2020 14:03:43
User entered 'FRACTURE OCCURED DURING THE SEXUAL ASSUALT.'	Christina Bacher (b) (4)	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 14:03:12

US3632127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:08:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 14:03:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Source lists subject as taking Naproxen ongoing, with a start date of 07Nov2020. This is missing from EDC ConMed list. Please add medication to EDC. ' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:14
Query 'According to AE page, a concomitant procedure was completed. Please complete the Concomitant Procedures page in EDC.' answered with 'updated' (Site from CRA).	Catherine Abrams (b) (4) (b) (4)	19 Nov 2020 21:21:43
User opened query 'According to AE page, a concomitant procedure was completed. Please complete the Concomitant Procedures page in EDC.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	18 Nov 2020 15:31:00
User opened query 'Source lists subject as taking Naproxen ongoing, with a start date of 07Nov2020. This is missing from EDC ConMed list. Please add medication to EDC. ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	17 Nov 2020 18:14:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	17 Nov 2020 17:26:19
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 20:46:45

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:28:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:52:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:52:17
Data point term sent to Coder User entered 'Lisinopril HCTZ'	System (b) (4), (b) (6)	13 Oct 2020 20:51:40 13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:28:40
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:53
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:29:55
User entered '10/12.5'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:00
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:36:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:36:44
User entered 'mg (mg)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:36:44
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:51:02
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:02
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:05
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:07
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:30:10
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:31
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:39
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:52
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:50
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:31:47
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:32:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:51:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:05:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:05:29
Data point term sent to Coder	System	13 Oct 2020 20:51:40
User entered 'Fish Oils'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:18
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:20
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:22
User entered '360'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:23
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:29
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:35
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:37
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:39
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:51:29

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:53:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:53:33
Data point term sent to Coder	System	13 Oct 2020 20:52:41
User entered 'Aspirin'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:33:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:16
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:43
User entered '81'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:45
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:47
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:55
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:34:57
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:07
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:11
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:17
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:51:53

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:22
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:25:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:25:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:04:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:04:36
Data point term sent to Coder	System	13 Oct 2020 20:52:45
User entered 'Turmeric'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:35:37
User entered 'Osteoarthritis'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:39:08
User entered '538'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:39:11
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:39:19
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:39:23
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:39:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:39:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:40:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:40:10
User entered '1 UNK 2010'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:40:25
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:40:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:42:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:42:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:52:26

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:47:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 08:47:27
Data point term sent to Coder	System	13 Oct 2020 20:53:49
User entered 'Naproxen Oral Suspension'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:14
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:18
User entered 'Osteoarthritis'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:27
User entered '1.25/5'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:45:30
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:02
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:05
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:10
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:12
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:15
User entered '1 UNK 2005'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:48:16
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:37:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:37:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Likos (b) (4) (b) (4)	14 Oct 2020 12:37:02
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:53:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 20:53:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:50:00
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:53:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), COMBINATIONS, PRODUCT: ASCORBIC ACID; ROSA CANINA; SODIUM ASCORBATE, PRODUCTSYNONYM: POWER C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:29:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:29:30
Data point term sent to Coder	System	13 Oct 2020 20:54:51
User entered 'Power C Gummies'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:51:59
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:10
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:13
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:52:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:52:03
User entered '2' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:52:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	13 Oct 2020 20:54:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:18
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:52:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:52:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:52:03
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:54:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:19
User entered 'gummies' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:52:03
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:21
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:23
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:31
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:52:50
User entered '1 Feb 2020'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:14
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:27
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:54:32

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: VACCINIUM MACROCARPON, PRODUCTSYNONYM: CRANBERRY [VACCINIUM MACROCARPON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
Data point term sent to Coder User entered 'Cranberry'	System (b) (4), (b) (6)	13 Oct 2020 20:55:52 13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:39
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:41
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:46
User entered '4200'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:49
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:53
User entered 'twice daily (BID)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:54
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:53:58
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:02
User entered '1 UNK 2005'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:06
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:09
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:55:00

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
Data point term sent to Coder	System	13 Oct 2020 20:55:52
User entered 'Potassium'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:20
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:23
User entered 'Hypertension'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:54:25
User entered '10'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:26
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:28
User entered 'MeQ'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:33
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:37
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:40
User entered '1 Apr 2020'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:42
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:45
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:55:47
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:55:35

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 20:57:18
Data point term sent to Coder	System	13 Oct 2020 20:56:54
User entered 'Magnesium'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:38:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:38:13
User entered 'No (N)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:38:13
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:56:12
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:46
User entered 'Constipation'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:49
User entered '400'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:51
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:57
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:56:59
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:03
User entered '1 Apr 2020'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:04
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:09
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:11
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:56:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:59:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:59:19
Data point term sent to Coder	System	13 Oct 2020 20:57:56
User entered 'Probiotic'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:19
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:23
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:34
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:44:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:44:35
User entered '2' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:44:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	13 Oct 2020 20:57:20
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:37
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 12:44:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:44:35
User entered 'capsule (CAPSULE)' reason for change: Data Entry Error	Kelly Likos (b) (4)	14 Oct 2020 12:44:35
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:57:20
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:40
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:45
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:53
User entered '1 UNK 2015'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:57:57
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:16
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:57:20

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:32
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: MALUS SPP. VINEGAR EXTRACT, PRODUCTSYNONYM: APPLE CIDER VINEGAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 21:00:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 21:00:17
Data point term sent to Coder	System	13 Oct 2020 20:58:57
User entered 'Apple Cider Vinegar'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:36
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:38
User entered '480'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:40
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:42
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:48
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:51
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:53
User entered '1 UNK 2018'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:55
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:00
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:57:58

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:11
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SAMBUCUS NIGRA, PRODUCTSYNONYM: ELDERBERRY [SAMBUCUS NIGRA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 21:00:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 21:00:17
Data point term sent to Coder	System	13 Oct 2020 20:58:57
User entered 'Elderberry'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:14
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:16
User entered 'General Health'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:18
User entered '1250'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:20
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:21
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:30
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:32
User entered '1 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:34
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:39
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:41
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 20:58:28

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:16:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:16:40
Data point term sent to Coder User entered 'Naproxen'	System Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:34 20 Oct 2020 15:15:17

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:55
User entered 'No (N)'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:00
User entered 'Pain'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:03
User entered '500'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:04
User entered 'mg (mg)'	Bezuayehu Mandefro (b) (4)	20 Oct 2020 15:15:17

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:06
User entered empty.	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:08
User entered 'once (ONCE)'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:10
User entered empty.	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:12
User entered 'Oral (ORAL)'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:14
User entered empty.	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:16
User entered '13 Oct 2020'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:19
User entered '0'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:23
User entered 'No (N)'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:27
User entered '13 Oct 2020'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:03:32
User entered 'No (N)'	Bezuayehu Mandefro	20 Oct 2020 15:15:17
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:15:17

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:15:17

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 15:15:17

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:01:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:22
Data point term sent to Coder	System	03 Nov 2020 13:24:29
User entered 'Pravastatin'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:01:29
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:01:42
User entered 'Slightly Elevated Cholesterol'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:01:44
User entered '10'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:01:46
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:06
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:07
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:12
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:15
User entered '19 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:17
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:30
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:02:33
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 13:24:03

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:26
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) (b) (4)	03 Nov 2020 16:13:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 16:13:21
Data point term sent to Coder	System	03 Nov 2020 16:12:04
User entered 'Vitamin D3'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:27
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:30
User entered 'To help with bone health'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:33
User entered '5000'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:35
User entered 'IU (IU)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:37
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:19
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:04:39
User entered 'every week (QS)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:21
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:25
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:28
User entered '01 May 2020'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:31
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:35
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:37
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	03 Nov 2020 16:12:01

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC SODIUM, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:54:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:54:38
Data point term sent to Coder	System	03 Nov 2020 19:24:51
User entered 'VOLTAREN GEL (Diclofenac Sodium 1% Gel)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 19:24:33
Data point term sent to Coder	System	03 Nov 2020 16:13:05
User entered 'Voltaren Gel'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:50
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:56
User entered 'Rheumatoid Arthritis'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:05:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 19:24:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 19:24:33
User entered '2' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 19:24:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:00
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 19:24:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 19:24:33
User entered 'g (g)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 19:24:33
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 16:12:42
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:03
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:05
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:08
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:10
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:11
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:14
User entered '01 UNK 2019'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:16
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:22
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 16:12:42

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:10:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:10:35
Data point term sent to Coder	System	20 Nov 2020 14:57:27
Coding entries removed.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:56:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:29:43
Data point term sent to Coder	System	10 Nov 2020 21:34:07
User entered 'Ceftriaxone'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:06:33
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
Query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly.' answered with 'UPDATED' (Site from CRA).	Christina Bacher (b) (4)	20 Nov 2020 14:56:53
User entered 'Sexual assault (AE)- presumptive treatment of STI's' reason for change: New Information	Christina Bacher (b) (4)	20 Nov 2020 14:56:47
User opened query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:08:11
User entered 'presumptive treatment for STI'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:15
User entered '250'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:17
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:19
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:29
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:32
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:35
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:38
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:39
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:08:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:27

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 05:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 05:24:43
Data point term sent to Coder	System	20 Nov 2020 14:57:28
Coding entries removed.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:57:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:09:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:41:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 04:41:49
Data point term sent to Coder	System	10 Nov 2020 21:37:10
User entered 'Zithromax'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:09:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
Query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' answered with 'updated' (Site from CRA).	Christina Bacher (b) (4)	20 Nov 2020 14:57:29
User entered 'SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S' reason for change: New Information	Christina Bacher (b) (4)	20 Nov 2020 14:57:21
User opened query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:10:18
User entered 'presumptive treatment for STI'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:22
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:23
User entered 'g (g)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:28
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:29
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:31
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:32
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:34
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:36
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:43
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:48
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:10:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:36:38

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:29:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:29:54
Data point term sent to Coder	System	20 Nov 2020 14:58:29
Coding entries removed.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:57:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:50:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:50:44
Data point term sent to Coder	System	10 Nov 2020 21:38:13
User entered 'Flagyl'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:04
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
Query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' answered with 'UPDATED' (Site from CRA).	Christina Bacher (b) (4)	20 Nov 2020 14:57:55
User entered 'SEXUAL ASSAULT (AE)- PRESUMPTIVE TREATMENT OF STI'S' reason for change: New Information	Christina Bacher (b) (4)	20 Nov 2020 14:57:48
User opened query 'Per source, indication is for the AE of Sexual Assault. Please verify with source and update indication in EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:11:19
User entered 'presumptive treatment for STI'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:27
User entered '2'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:28
User entered 'g (g)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:32
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:34
User entered 'once (ONCE)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:36
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:40
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:42
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:44
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:50
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:55
User entered '07 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:11:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:38:05

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:12:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: OTHER ANTIVIRALS, PRODUCT: DOLUTEGRAVIR SODIUM, PRODUCTSYNONYM: TIVICAY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:11:41
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 Nov 2020 05:11:41
Data point term sent to Coder	System	13 Nov 2020 19:53:44
User entered 'Tivicay (dolutegravir)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:25
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:28
User entered 'Sexual Assault (AE #1)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:31
User entered '50'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:33
User entered 'mg (mg)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:38
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:40
User entered 'once daily (QD)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:41
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:44
User entered 'Oral (ORAL)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:46
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:14:48
User entered '12 Nov 2020'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:56
User entered '0'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:58
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:59
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:16:01
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 19:53:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Nov 2020 19:53:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 19:53:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 19:53:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Nov 2020 19:52:57
User entered empty.	System	13 Nov 2020 19:52:57
	Aastha KC (b) (4)	13 Nov 2020 19:52:57
	(b) (4)	

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 19:52:57

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:50:45
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 Nov 2020 05:50:45
Data point term sent to Coder	System	13 Nov 2020 19:55:48
User entered 'emtricitabine and tenofovir disoproxil fumarate'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:08
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:10
User entered 'Sexual Assault'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:12
User entered '200/300'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:14
User entered 'mg (mg)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:16
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:17
User entered 'once daily (QD)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:18
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:21
User entered 'Oral (ORAL)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:23
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:25
User entered '12 Nov 2020'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:26
User entered '0'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:30
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:17:28
User entered 'Yes (Y)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:23:29
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 18:21:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:21:28
User entered 'No (N)'	Aastha KC (b) (4) (b) (4)	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 19:55:12

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:06:04
Data point term sent to Coder	System	20 Nov 2020 14:55:25
User entered 'Naproxen'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Indication](#)

Audit	User	Time (GMT)
User entered 'Fractured toe (AE)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Nov 2020'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:08:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Nov 2020 14:55:02

US3632127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 14:59:38

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:44
User entered '11/Nov/2020 20:57'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:53
User entered '16/Nov/2020 09:58'	System	16 Nov 2020 14:58:35

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:08:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 15:42:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:55
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 14:58:35

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'USA-US120-2020-MRNA-1273-P301000004'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:10:31
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:14:06
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'No (N)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:17:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Yes (Y)'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Colleen'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:23
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'Kelley'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:57:18
User entered 'GA'	System	11 Nov 2020 20:57:02

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:18:39
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:58:19
User entered 'US'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 15:43:00
User entered '2'	System	16 Nov 2020 14:58:35
User entered '1'	System	11 Nov 2020 20:57:25

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:08:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '20/Nov/2020 10:42'	System	20 Nov 2020 15:43:00

US3632127

Folder: SAE USA-US120-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:08:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 15:43:00