

US3252602 (Prod: Centex Studies Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:53:09

All time stamps listed in this document are displayed in GMT

US3252602

Form: Participant Creation

Generated On: 26 Nov 2020 10:53:09

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:53:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:53:09

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

Condition	LUMBAR RADICULOPATHY
Start date (dd MMM yyyy)	UN SEP 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2010
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2010
Start Year (derived)	2010
Stop Month and Year (derived)	SEP 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN SEP 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2012
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

Condition	OOPHORECTOMY
Start date (dd MMM yyyy)	UN SEP 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2012
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

Condition	BENIGN UTERINE TUMOR
Start date (dd MMM yyyy)	UN SEP 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2012
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

Condition	BENIGN TUMOR ON LEFT BREAST
Start date (dd MMM yyyy)	UN SEP 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2001
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2001
Start Year (derived)	2001
Stop Month and Year (derived)	SEP 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

Condition	EXTRACTION OF BENIGN TUMOR ON LEFT BREAST
Start date (dd MMM yyyy)	UN SEP 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	UN SEP 2001
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2001
Start Year (derived)	2001
Stop Month and Year (derived)	SEP 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

Condition	ALLERGY TO BACTRIM
Start date (dd MMM yyyy)	UN SEP 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:16 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:16
Height (<i>xxx.x</i>)	66.5 in
Weight (<i>xxx.x</i>)	151.8 lb
BMI (<i>xxx.x</i>)	24.18457 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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 10:53:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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 10:53:09

Date of assessment (<i>dd MMM yyyy</i>)	2 OCT 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	UN SEP 2012
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

What was the date of randomization? (dd MMM yyyy) 02 OCT 2020

What was the participant's randomization number? 116298

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 10:53:09

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 10:53:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:16
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 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 10:53:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 11:31
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	2 OCT 2020
What was the treatment time? (00:00-23:59)	11:01 (24 HR)
Treatment Date and Time (derived)	2 OCT 2020 11:01
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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 10:53:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	2 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:53 (24 HR)
Collection date and time (derived)	2 OCT 2020 10:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:09

Collection date (<i>dd MMM yyyy</i>)			2 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	10:48	2 OCT 2020 10:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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 10:53:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 02 OCT 2020 11:34

PC Open Date & Time 02 OCT 2020 11:21

PC Close Date & Time 02 OCT 2020 13:51

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	02 OCT 2020 21:08
PC Open Date & Time	02 OCT 2020 14:46
PC Close Date & Time	03 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 21:43

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

97.2 °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

04 OCT 2020 22:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 21:47

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 23:53

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

07 OCT 2020 21:35

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

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

08 OCT 2020 22:45

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

02 OCT 2020 11:35

PC Open Date & Time

02 OCT 2020 11:21

PC Close Date & Time

02 OCT 2020 13:51

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

02 OCT 2020 21:09

PC Open Date & Time

02 OCT 2020 14:46

PC Close Date & Time

03 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

03 OCT 2020 21:44

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

04 OCT 2020 22:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

05 OCT 2020 21:48

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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

06 OCT 2020 23:54

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

07 OCT 2020 21:36

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

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

08 OCT 2020 22:45

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 11:36
PC Open Date & Time	02 OCT 2020 11:21
PC Close Date & Time	02 OCT 2020 13:51

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 21:10
PC Open Date & Time	02 OCT 2020 14:46
PC Close Date & Time	03 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 21:45
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 22:05
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 21:49
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 23:56
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 21:37
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 22:46
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 09 OCT 2020 23:20

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp 10 OCT 2020 22:08

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 11 OCT 2020 21:20

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 12 OCT 2020 19:54

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 13 OCT 2020 19:26

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 09 OCT 2020 23:20

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 10 OCT 2020 22:08

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 11 OCT 2020 21:20

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 12 OCT 2020 19:54

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

13 OCT 2020 19:26

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 14 OCT 2020 13:43

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

15 OCT 2020 14:22

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 16 OCT 2020 20:52

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 OCT 2020 21:27

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 18 OCT 2020 19:59

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 OCT 2020 20:00

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 OCT 2020 13:44

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 22 OCT 2020 10:34

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 22 OCT 2020 21:02

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 23 OCT 2020 20:07

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 24 OCT 2020 13:07

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

25 OCT 2020 12:22

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 26 OCT 2020 12:34

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

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 09 OCT 2020 23:20

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 9

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 10 OCT 2020 22:08

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 10

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 11 OCT 2020 21:20

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 11

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 12 OCT 2020 19:54

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 12

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	13 OCT 2020 19:26
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PC Open Date & Time	13 OCT 2020 12:00
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PC Close Date & Time	14 OCT 2020 11:59
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US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 13

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 14 OCT 2020 13:43

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 14

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 15 OCT 2020 14:22

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 15

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 16 OCT 2020 20:53

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 16

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 17 OCT 2020 21:28

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 17

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 18 OCT 2020 19:59

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 18

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 19 OCT 2020 20:00

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 19

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 13:44

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 20

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 22 OCT 2020 10:35

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 21

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 22 OCT 2020 21:02

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 22

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 23 OCT 2020 20:07

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 23

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 24 OCT 2020 13:07

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 24

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 25 OCT 2020 12:22

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 25

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 OCT 2020 12:34

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 26

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 27

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp	09 OCT 2020 23:21
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PC Open Date & Time	09 OCT 2020 12:00
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PC Close Date & Time	10 OCT 2020 11:59
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US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp	10 OCT 2020 22:08
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PC Open Date & Time	10 OCT 2020 12:00
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PC Close Date & Time	11 OCT 2020 11:59
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US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 11 OCT 2020 21:21

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 12 OCT 2020 19:55

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 OCT 2020 19:26

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 14 OCT 2020 13:43

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 15 OCT 2020 14:22

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 OCT 2020 20:53

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 OCT 2020 21:28

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 OCT 2020 19:59

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 OCT 2020 20:00

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 OCT 2020 13:44

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	22 OCT 2020 10:35
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PC Open Date & Time	21 OCT 2020 12:00
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PC Close Date & Time	22 OCT 2020 11:59
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US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	22 OCT 2020 21:02
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PC Open Date & Time	22 OCT 2020 12:00
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PC Close Date & Time	23 OCT 2020 11:59
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US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 20:07

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 OCT 2020 13:08

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 OCT 2020 12:22

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 OCT 2020 12:34

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 26

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 27

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 09 OCT 2020 23:21

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp 10 OCT 2020 22:08

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 23:21
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 22:08
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 21:21
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 OCT 2020 19:55
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 OCT 2020 19:26
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 13:43
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 14:23
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 20:53
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 21:28
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 19:59
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 OCT 2020 20:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 13:44
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 10:35
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 21:02
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 20:07
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 13:08
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 12:22
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 12:34
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 26

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 27

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 8

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 09 OCT 2020 23:22

PC Open Date and Time 09 OCT 2020 12:00

PC Close Date and Time 10 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 9

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 10 OCT 2020 22:08

PC Open Date and Time 10 OCT 2020 12:00

PC Close Date and Time 11 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 10

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 11 OCT 2020 21:21

PC Open Date and Time 11 OCT 2020 12:00

PC Close Date and Time 12 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 11

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 OCT 2020 19:55

PC Open Date and Time 12 OCT 2020 12:00

PC Close Date and Time 13 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 12

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 OCT 2020 19:27

PC Open Date and Time 13 OCT 2020 12:00

PC Close Date and Time 14 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 13

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 13:43

PC Open Date and Time 14 OCT 2020 12:00

PC Close Date and Time 15 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 14

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 14:23

PC Open Date and Time 15 OCT 2020 12:00

PC Close Date and Time 16 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 15

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 20:53

PC Open Date and Time 16 OCT 2020 12:00

PC Close Date and Time 17 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 16

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 17 OCT 2020 21:28

PC Open Date and Time 17 OCT 2020 12:00

PC Close Date and Time 18 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 17

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 18 OCT 2020 19:59

PC Open Date and Time 18 OCT 2020 12:00

PC Close Date and Time 19 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 18

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 20:01

PC Open Date and Time 19 OCT 2020 12:00

PC Close Date and Time 20 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 19

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 20 OCT 2020 13:45

PC Open Date and Time 20 OCT 2020 12:00

PC Close Date and Time 21 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 20

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 22 OCT 2020 10:35

PC Open Date and Time 21 OCT 2020 12:00

PC Close Date and Time 22 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 21

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 22 OCT 2020 21:02

PC Open Date and Time 22 OCT 2020 12:00

PC Close Date and Time 23 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 22

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 23 OCT 2020 20:07

PC Open Date and Time 23 OCT 2020 12:00

PC Close Date and Time 24 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 23

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 24 OCT 2020 13:08

PC Open Date and Time 24 OCT 2020 12:00

PC Close Date and Time 25 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 24

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 25 OCT 2020 12:23

PC Open Date and Time 25 OCT 2020 12:00

PC Close Date and Time 26 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 25

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 26 OCT 2020 12:35

PC Open Date and Time 26 OCT 2020 12:00

PC Close Date and Time 27 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 26

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

27 OCT 2020 12:00

PC Close Date and Time

28 OCT 2020 11:59

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 27

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

28 OCT 2020 12:00

PC Close Date and Time

29 OCT 2020 11:59

US3252602

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

Was Contact Attempted?

Yes ☒

No ☐

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

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252602

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

Was Contact Attempted?

Yes ☒

No ☐

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

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252602

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

Was Contact Attempted?

Yes ☒

No ☐

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

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252602

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	09:18 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 09:18
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 10:16
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3252602

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	30 OCT 2020
What was the treatment time? (00:00-23:59)	09:46 (24 HR)
Treatment Date and Time (derived)	30 OCT 2020 09:46
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3252602

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:37 (24 HR)
Collection date and time (derived)	30 OCT 2020 09:37

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:09

Collection date (<i>dd MMM yyyy</i>)			30 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	09:38	30 OCT 2020 09:38
Nasopharyngeal Swab 2	No		

US3252602

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 10:20

PC Open Date & Time

30 OCT 2020 10:06

PC Close Date & Time

30 OCT 2020 12:36

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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 ☒

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 30 OCT 2020 16:44

PC Open Date & Time 30 OCT 2020 13:31

PC Close Date & Time 31 OCT 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

95.7 °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

01 NOV 2020 00:30

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

01 NOV 2020 21:09

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

96.1 °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

02 NOV 2020 20:48

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

03 NOV 2020 20:36

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

04 NOV 2020 22:47

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

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

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

30 OCT 2020 10:21

PC Open Date & Time

30 OCT 2020 10:06

PC Close Date & Time

30 OCT 2020 12:36

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

30 OCT 2020 16:45

PC Open Date & Time

30 OCT 2020 13:31

PC Close Date & Time

31 OCT 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

01 NOV 2020 00:31

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

01 NOV 2020 21:09

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

02 NOV 2020 20:48

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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

03 NOV 2020 20:36

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

04 NOV 2020 22:48

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 10:21
PC Open Date & Time	30 OCT 2020 10:06
PC Close Date & Time	30 OCT 2020 12:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 16:45
PC Open Date & Time	30 OCT 2020 13:31
PC Close Date & Time	31 OCT 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 00:31
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 21:10
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 20:49
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 20:37
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 ☒

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 22:48
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		05 NOV 2020 12:00
PC Close Date & Time		06 NOV 2020 11:59
<hr/>		

US3252602

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	06 NOV 2020 17:35
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3252602

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 8

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 06 NOV 2020 17:35

PC Open Date and Time 06 NOV 2020 12:00

PC Close Date and Time 07 NOV 2020 11:59

US3252602

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

Was Contact Attempted?

Yes ☒

No ☐

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

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252602

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

Was Contact Attempted?

Yes ☒

No ☐

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

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VOICE MAIL

If Contact Not Made, please provide Comments

US3252602

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

Was Contact Attempted?

Yes ☒

No ☐

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

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252602

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252602

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3252602

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3252602

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3252602

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3252602

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:53:09

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3252602

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:53:09

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252602

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:53:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

AEID	USA-US108-2020-MRNA-1273-P30 1000016
Adverse event	APPENDICITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	6 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	6 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	6 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	443 of 2208

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT GOT APPENDICITIS TODAY AND GOT AN APPENDECTOMY.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:53:09

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

Yes ☒

No ☐

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

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

Name of Medication	NAPROXEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LUMBAR RADICULOPATHY
Dose per administration	375
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

Name of Medication	CYCLOBENZAPRINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LUMBAR RADICULOPATHY
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	28 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LUMBAR RADICULOPATHY
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

Name of Medication	ALENDRONATE SODIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOPENIA
Dose per administration	35
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input checked="" type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input checked="" type="radio"/>
	804 <input type="radio"/>

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:53:09

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:53:09

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
6 NOV 2020	APPENDECTOMY	Adverse Event	

US3252602

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:53:09

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

US3252602

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:53:09

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 ☐

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

SAEID	USA-US108-2020-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:53:09

SAEID	USA-US108-2020-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/NOV/2020 14:39
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

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:53:09

SAEID	USA-US108-2020-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:45
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.	<input checked="" type="checkbox"/> True

Audit

US3252602 (Prod: Centex Studies Inc)

US3252602

Form: Participant Creation

Generated On: 26 Nov 2020 10:53:09

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3252602'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Oct 2020 15:27:47

US3252602

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:38

US3252602

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Oct 2020 15:27:49

US3252602

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:38

US3252602

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	02 Oct 2020 16:00:38

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Oct 2020 15:27:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

Age

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 18:43:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 18:43:00
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	02 Oct 2020 18:43:00
User entered '52' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 18:43:00
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 16:00:50
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	02 Oct 2020 16:00:50
User entered empty.	Joanna Gurrola (b) (4)	02 Oct 2020 16:00:50
	(b) (4)	

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	02 Oct 2020 18:43:00
User entered empty.	System	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '52'	System	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

White

Audit	User	Time (GMT)
User entered 'I'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

Unknown

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:53:09

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:00:50

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:26

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Oct 2020 15:27:49

US3252602

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:53:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 16:01:41

US3252602

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:41

US3252602

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:53:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:57:47

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 03:59:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 03:59:58
Data point term sent to Coder	System	03 Oct 2020 03:58:41
User entered 'Osteopenia'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2020'	System	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 03:58:37

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Lumbar radiculopathy, LLT: Lumbar radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:00:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:00:59
Data point term sent to Coder	System	03 Oct 2020 03:59:41
User entered 'Lumbar Radiculopathy'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2010'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2010'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2010'	System	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2010'	System	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2010'	System	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2010'	System	03 Oct 2020 03:59:25

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:02:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:02:47
Data point term sent to Coder	System	03 Oct 2020 04:01:41
User entered 'Hysterectomy'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Start date of MH = UN SEP 2012. However, Surgically sterile date recorded in Childbearing ecf is UN UNK 2012 Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:03:17
Query 'Per DM CLR: Please note, Start date of MH = UN SEP 2012. However, Surgically sterile date recorded in Childbearing ecf is UN UNK 2012 Review and reconcile dates as appropriate. Else, clarify. ' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:05:24
User opened query 'Per DM CLR: Please note, Start date of MH = UN SEP 2012. However, Surgically sterile date recorded in Childbearing ecf is UN UNK 2012 Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:52:22
User entered 'UN Sep 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Oct 2020 04:01:02

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy, LLT: Oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 04:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 04:03:49
Data point term sent to Coder	System	03 Oct 2020 04:02:42
User entered 'Oophorectomy'	Shannon Moyer (b) (4)	03 Oct 2020 04:01:46
	(b) (4)	

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Start date of MH = UN SEP 2012. However, Surgically sterile date recorded in Childbearing ecf is UN UNK 2012 Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:03:46
Query 'Per DM CLR: Please note, Start date of MH = UN SEP 2012. However, Surgically sterile date recorded in Childbearing ecf is UN UNK 2012 Review and reconcile dates as appropriate. Else, clarify. ' answered with 'DATA UPDATED ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:05:45
User opened query 'Per DM CLR: Please note, Start date of MH = UN SEP 2012. However, Surgically sterile date recorded in Childbearing ecf is UN UNK 2012 Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:53:01
User entered 'UN Sep 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Oct 2020 04:01:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Benign uterine neoplasm, LLT: Benign uterine neoplasm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:04:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:04:58
Data point term sent to Coder	System	03 Oct 2020 04:03:42
User entered 'Benign Uterine Tumor'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2012'	System	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Oct 2020 04:02:46

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Breast tumor benign - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:19:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:19:43
Data point term sent to Coder	System	03 Oct 2020 04:03:42
User entered 'Benign Tumor on Left Breast'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2001'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 04:03:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 04:03:45
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	03 Oct 2020 04:03:45
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 04:03:39
User entered empty.	Shannon Moyer (b) (4)	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2001'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2001'	System	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2001'	System	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2001'	System	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2001'	System	03 Oct 2020 04:03:39

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast neoplasm removal, PT: Breast tumour excision, LLT: Breast tumor excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:09:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:09:46
Data point term sent to Coder	System	03 Oct 2020 04:04:43
User entered 'Extraction of Benign Tumor on Left Breast'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2001'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2001'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2001'	System	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2001'	System	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2001'	System	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2001'	System	03 Oct 2020 04:04:42

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

[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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:08:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:08:47
Data point term sent to Coder	System	03 Oct 2020 04:07:44
User entered 'Allergy to Bactrim'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2004'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Sep 2004'	System	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2004'	System	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 04:07:29

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '10:16'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 10:16'	System	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Height (xxx.x)

Audit	User	Time (GMT)
User entered '66.5' in	Shannon Moyer (b) (4)	03 Oct 2020 04:09:15
DataPoint set to visible.	(b) (4) System	02 Oct 2020 16:01:41

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '151.8' lb	Shannon Moyer (b) (4)	03 Oct 2020 04:09:15
DataPoint set to visible.	(b) (4) System	02 Oct 2020 16:01:41

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '24.18457'	System	03 Oct 2020 04:09:15
DataPoint set to visible.	System	02 Oct 2020 16:01:41

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Oct 2020 04:09:15
DataPoint set to visible.	System	02 Oct 2020 16:01:41

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:53:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Oct 2020 04:09:15

US3252602

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:55

US3252602

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:01:55

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'UN Sep 2012' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 13:05:08
User entered 'UN UNK 2012'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:53:09

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:10:09

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:53:09

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 16:24:47

US3252602

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 16:17:38

US3252602

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 16:17:38

US3252602

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Oct 2020 16:17:38

US3252602

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	02 Oct 2020 16:17:38

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '02 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Oct 2020 15:27:52

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '116298'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Oct 2020 15:27:52

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	02 Oct 2020 15:27:52

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:18:08

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:18:08

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:18:08

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:18:08

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:18:08

US3252602

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 16:18:08
DataPoint set to visible.	System	02 Oct 2020 16:01:26

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:09

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:09

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:09

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:09

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '10:16'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 10:16'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Pulse (xxx)

Audit	User	Time (GMT)
User entered '71'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '15'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:09

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:53:09

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '11:31'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 11:31'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Pulse (xxx)

Audit	User	Time (GMT)
User entered '67'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '16'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Oct 2020 04:13:27

US3252602

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:36

US3252602

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:13:36

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '11:01'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 11:01'	System	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 16:02:18

US3252602

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:11

US3252602

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:11

US3252602

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:53'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:11

US3252602

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 10:53'	System	03 Oct 2020 04:14:11

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:48'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '2 Oct 2020 10:48'	System	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 04:14:38

US3252602

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:14:47

US3252602

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 04:14:47

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:25:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5636c377-4923-4323-a08b-e28bdbe85b2b'	System	02 Oct 2020 16:34:45
User entered 'Yes (Y)'	System	02 Oct 2020 16:34:45

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:34:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5636c377-4923-4323-a08b-e28bdbe85b2b'	System	02 Oct 2020 16:34:45
User entered '97.3'	System	02 Oct 2020 16:34:45

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:34:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5636c377-4923-4323-a08b-e28bdbe85b2b'	System	02 Oct 2020 16:34:45
User entered 'No (N)'	System	02 Oct 2020 16:34:45

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:34:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5636c377-4923-4323-a08b-e28bdbe85b2b'	System	02 Oct 2020 16:34:45
User entered '02 Oct 2020 11:34'	System	02 Oct 2020 16:34:45

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:21'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:51'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:05:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '55dbacbe-2879-409d-83f3-0ce835c4a7b3'	System	03 Oct 2020 02:08:30
User entered 'Yes (Y)'	System	03 Oct 2020 02:08:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '55dbacbe-2879-409d-83f3-0ce835c4a7b3'	System	03 Oct 2020 02:08:30
User entered '97.3'	System	03 Oct 2020 02:08:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '55dbacbe-2879-409d-83f3-0ce835c4a7b3'	System	03 Oct 2020 02:08:30
User entered 'No (N)'	System	03 Oct 2020 02:08:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:27', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '55dbacbe-2879-409d-83f3-0ce835c4a7b3'	System	03 Oct 2020 02:08:30
User entered '02 Oct 2020 21:08'	System	03 Oct 2020 02:08:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 14:46'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 2'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:43:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'acd48d32-8dbe-418b-a68c-4774b6cf0083'	System	04 Oct 2020 02:43:42
User entered 'Yes (Y)'	System	04 Oct 2020 02:43:42

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:43:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'acd48d32-8dbe-418b-a68c-4774b6cf0083'	System	04 Oct 2020 02:43:42
User entered '97.9'	System	04 Oct 2020 02:43:42

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:43:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'acd48d32-8dbe-418b-a68c-4774b6cf0083'	System	04 Oct 2020 02:43:42
User entered 'No (N)'	System	04 Oct 2020 02:43:42

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:43:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'acd48d32-8dbe-418b-a68c-4774b6cf0083'	System	04 Oct 2020 02:43:42
User entered '03 Oct 2020 21:43'	System	04 Oct 2020 02:43:42

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 3'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:02:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b88987cf-77ea-4ada-a316-e0aa8672e076'	System	05 Oct 2020 03:03:49
User entered 'Yes (Y)'	System	05 Oct 2020 03:03:49

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:03:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b88987cf-77ea-4ada-a316-e0aa8672e076'	System	05 Oct 2020 03:03:49
User entered '97.2'	System	05 Oct 2020 03:03:49

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:03:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b88987cf-77ea-4ada-a316-e0aa8672e076'	System	05 Oct 2020 03:03:49
User entered 'No (N)'	System	05 Oct 2020 03:03:49

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:03:45', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b88987cf-77ea-4ada-a316-e0aa8672e076'	System	05 Oct 2020 03:03:49
User entered '04 Oct 2020 22:03'	System	05 Oct 2020 03:03:49

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 4'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:46:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1fb92e67-f224-463d-b387-ac925961eb66'	System	06 Oct 2020 02:47:30
User entered 'Yes (Y)'	System	06 Oct 2020 02:47:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:47:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1fb92e67-f224-463d-b387-ac925961eb66'	System	06 Oct 2020 02:47:30
User entered '97.5'	System	06 Oct 2020 02:47:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:47:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1fb92e67-f224-463d-b387-ac925961eb66'	System	06 Oct 2020 02:47:30
User entered 'No (N)'	System	06 Oct 2020 02:47:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:47:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1fb92e67-f224-463d-b387-ac925961eb66'	System	06 Oct 2020 02:47:30
User entered '05 Oct 2020 21:47'	System	06 Oct 2020 02:47:30

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 5'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:52:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '192db000-2768-4069-a47e-0b1d2b7fae2c'	System	07 Oct 2020 04:53:46
User entered 'Yes (Y)'	System	07 Oct 2020 04:53:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:52:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '192db000-2768-4069-a47e-0b1d2b7fae2c'	System	07 Oct 2020 04:53:46
User entered '97.0'	System	07 Oct 2020 04:53:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:53:37', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '192db000-2768-4069-a47e-0b1d2b7fae2c'	System	07 Oct 2020 04:53:46
User entered 'No (N)'	System	07 Oct 2020 04:53:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:53:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '192db000-2768-4069-a47e-0b1d2b7fae2c'	System	07 Oct 2020 04:53:46
User entered '06 Oct 2020 23:53'	System	07 Oct 2020 04:53:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 6'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:34:27', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b23840c4-c429-4140-a81d-42c3771e47e5'	System	08 Oct 2020 02:35:46
User entered 'Yes (Y)'	System	08 Oct 2020 02:35:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:35:12', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b23840c4-c429-4140-a81d-42c3771e47e5'	System	08 Oct 2020 02:35:46
User entered '97.1'	System	08 Oct 2020 02:35:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:35:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b23840c4-c429-4140-a81d-42c3771e47e5'	System	08 Oct 2020 02:35:46
User entered 'No (N)'	System	08 Oct 2020 02:35:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:35:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b23840c4-c429-4140-a81d-42c3771e47e5'	System	08 Oct 2020 02:35:46
User entered '07 Oct 2020 21:35'	System	08 Oct 2020 02:35:46

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 7'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:44:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b48aa51e-5471-4353-bfc1-488d10123f19'	System	09 Oct 2020 03:45:15
User entered 'Yes (Y)'	System	09 Oct 2020 03:45:15

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:44:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b48aa51e-5471-4353-bfc1-488d10123f19'	System	09 Oct 2020 03:45:15
User entered '98.1'	System	09 Oct 2020 03:45:15

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b48aa51e-5471-4353-bfc1-488d10123f19'	System	09 Oct 2020 03:45:15
User entered 'No (N)'	System	09 Oct 2020 03:45:15

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b48aa51e-5471-4353-bfc1-488d10123f19'	System	09 Oct 2020 03:45:15
User entered '08 Oct 2020 22:45'	System	09 Oct 2020 03:45:15

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-02T11:34:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '362567bd-66cd-4378-84f7-58a608febb77'	System	02 Oct 2020 16:35:26
User entered 'None (1)'	System	02 Oct 2020 16:35:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '362567bd-66cd-4378-84f7-58a608febb77'	System	02 Oct 2020 16:35:26
User entered 'No (N)'	System	02 Oct 2020 16:35:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '362567bd-66cd-4378-84f7-58a608febb77'	System	02 Oct 2020 16:35:26
User entered 'No (N)'	System	02 Oct 2020 16:35:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '362567bd-66cd-4378-84f7-58a608febb77'	System	02 Oct 2020 16:35:26
User entered 'None (1)'	System	02 Oct 2020 16:35:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '362567bd-66cd-4378-84f7-58a608febb77'	System	02 Oct 2020 16:35:26
User entered '02 Oct 2020 11:35'	System	02 Oct 2020 16:35:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:21'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:51'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:44', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '683838b5-cdb6-407a-bea3-984a4b4a3024'	System	03 Oct 2020 02:09:19
User entered 'None (1)'	System	03 Oct 2020 02:09:19

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '683838b5-cdb6-407a-bea3-984a4b4a3024'	System	03 Oct 2020 02:09:19
User entered 'No (N)'	System	03 Oct 2020 02:09:19

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '683838b5-cdb6-407a-bea3-984a4b4a3024'	System	03 Oct 2020 02:09:19
User entered 'No (N)'	System	03 Oct 2020 02:09:19

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-02T21:08:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '683838b5-cdb6-407a-bea3-984a4b4a3024'	System	03 Oct 2020 02:09:19
User entered 'None (1)'	System	03 Oct 2020 02:09:19

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '683838b5-cdb6-407a-bea3-984a4b4a3024'	System	03 Oct 2020 02:09:19
User entered '02 Oct 2020 21:09'	System	03 Oct 2020 02:09:19

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 14:46'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 2'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-03T21:43:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '78798042-e754-44b5-a198-6fdeccf6c6a7'	System	04 Oct 2020 02:44:44
User entered 'None (1)'	System	04 Oct 2020 02:44:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:44:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '78798042-e754-44b5-a198-6fdeccf6c6a7'	System	04 Oct 2020 02:44:44
User entered 'No (N)'	System	04 Oct 2020 02:44:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:44:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '78798042-e754-44b5-a198-6fdeccf6c6a7'	System	04 Oct 2020 02:44:44
User entered 'No (N)'	System	04 Oct 2020 02:44:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-03T21:44:33', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '78798042-e754-44b5-a198-6fdeccf6c6a7'	System	04 Oct 2020 02:44:44
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 02:44:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:44:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '78798042-e754-44b5-a198-6fdeccf6c6a7'	System	04 Oct 2020 02:44:44
User entered '03 Oct 2020 21:44'	System	04 Oct 2020 02:44:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 3'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-04T22:03:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c87267e6-1acc-412e-9d7f-954546aaf91c'	System	05 Oct 2020 03:04:26
User entered 'None (1)'	System	05 Oct 2020 03:04:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:03:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c87267e6-1acc-412e-9d7f-954546aaf91c'	System	05 Oct 2020 03:04:26
User entered 'No (N)'	System	05 Oct 2020 03:04:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:03:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c87267e6-1acc-412e-9d7f-954546aaf91c'	System	05 Oct 2020 03:04:26
User entered 'No (N)'	System	05 Oct 2020 03:04:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c87267e6-1acc-412e-9d7f-954546aaf91c'	System	05 Oct 2020 03:04:26
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 03:04:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c87267e6-1acc-412e-9d7f-954546aaf91c'	System	05 Oct 2020 03:04:26
User entered '04 Oct 2020 22:04'	System	05 Oct 2020 03:04:26

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 4'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-05T21:47:32', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '04ec3afd-1740-4b94-b629-14aff192781a'	System	06 Oct 2020 02:48:32
User entered 'None (1)'	System	06 Oct 2020 02:48:32

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:47:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '04ec3afd-1740-4b94-b629-14aff192781a'	System	06 Oct 2020 02:48:32
User entered 'No (N)'	System	06 Oct 2020 02:48:32

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:47:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '04ec3afd-1740-4b94-b629-14aff192781a'	System	06 Oct 2020 02:48:32
User entered 'No (N)'	System	06 Oct 2020 02:48:32

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '04ec3afd-1740-4b94-b629-14aff192781a'	System	06 Oct 2020 02:48:32
User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 02:48:32

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '04ec3afd-1740-4b94-b629-14aff192781a'	System	06 Oct 2020 02:48:32
User entered '05 Oct 2020 21:48'	System	06 Oct 2020 02:48:32

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 5'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-06T23:53:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dae7924f-a2c8-4d7a-b336-b7cf183803d4'	System	07 Oct 2020 04:54:27
User entered 'None (1)'	System	07 Oct 2020 04:54:27

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:53:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dae7924f-a2c8-4d7a-b336-b7cf183803d4'	System	07 Oct 2020 04:54:27
User entered 'No (N)'	System	07 Oct 2020 04:54:27

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:53:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dae7924f-a2c8-4d7a-b336-b7cf183803d4'	System	07 Oct 2020 04:54:27
User entered 'No (N)'	System	07 Oct 2020 04:54:27

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-06T23:54:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dae7924f-a2c8-4d7a-b336-b7cf183803d4'	System	07 Oct 2020 04:54:27
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 04:54:27

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:54:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dae7924f-a2c8-4d7a-b336-b7cf183803d4'	System	07 Oct 2020 04:54:27
User entered '06 Oct 2020 23:54'	System	07 Oct 2020 04:54:27

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 6'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-07T21:35:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '977afd66-b49e-4d20-a432-bccf36ba0c47'	System	08 Oct 2020 02:36:31
User entered 'None (1)'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:35:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '977afd66-b49e-4d20-a432-bccf36ba0c47'	System	08 Oct 2020 02:36:31
User entered 'No (N)'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:35:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '977afd66-b49e-4d20-a432-bccf36ba0c47'	System	08 Oct 2020 02:36:31
User entered 'No (N)'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-07T21:36:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '977afd66-b49e-4d20-a432-bccf36ba0c47'	System	08 Oct 2020 02:36:31
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:36:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '977afd66-b49e-4d20-a432-bccf36ba0c47'	System	08 Oct 2020 02:36:31
User entered '07 Oct 2020 21:36'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 7'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4e8dbc40-d2a4-4d18-aaba-edabf3b089c0'	System	09 Oct 2020 03:45:44
User entered 'None (1)'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4e8dbc40-d2a4-4d18-aaba-edabf3b089c0'	System	09 Oct 2020 03:45:44
User entered 'No (N)'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:24', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4e8dbc40-d2a4-4d18-aaba-edabf3b089c0'	System	09 Oct 2020 03:45:44
User entered 'No (N)'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:30', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4e8dbc40-d2a4-4d18-aaba-edabf3b089c0'	System	09 Oct 2020 03:45:44
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4e8dbc40-d2a4-4d18-aaba-edabf3b089c0'	System	09 Oct 2020 03:45:44
User entered '08 Oct 2020 22:45'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:36', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'None (0)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'None (0)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'None (0)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'None (0)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:35:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'None (0)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:36:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'None (0)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-02T11:36:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered 'No (N)'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T11:36:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ce3cd45d-c694-4904-8fff-9cf30c51fe7a'	System	02 Oct 2020 16:36:23
User entered '02 Oct 2020 11:36'	System	02 Oct 2020 16:36:23

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:21'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 13:51'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'None (0)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:36', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'No interference with activity (1)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'No interference with activity (1)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'No interference with activity (1)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'None (0)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:09:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'None (0)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-02T21:10:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered 'No (N)'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-02T21:10:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4445bff5-836f-4062-a09b-fd91008a5477'	System	03 Oct 2020 02:10:25
User entered '02 Oct 2020 21:10'	System	03 Oct 2020 02:10:25

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 14:46'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 2'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:44:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'No interference with activity (1)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'Some interference with activity (2)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'Some interference with activity (2)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:17', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'Some interference with activity (2)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:22', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'None (0)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:25', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'None (0)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:32', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered 'No (N)'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-03T21:45:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dc14d152-4239-4775-a0a2-35c09546b31b'	System	04 Oct 2020 02:45:52
User entered '03 Oct 2020 21:45'	System	04 Oct 2020 02:45:52

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 3'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:33', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'Some interference with activity (2)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:37', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'Some interference with activity (2)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:44', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'Some interference with activity (2)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'None (0)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'None (0)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-04T22:04:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered 'No (N)'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-04T22:05:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '423ab807-c2e7-4cf6-8c18-3941e8c6a9a5'	System	05 Oct 2020 03:05:17
User entered '04 Oct 2020 22:05'	System	05 Oct 2020 03:05:17

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 4'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:36', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'No interference with activity (1)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:44', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'Some interference with activity (2)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'Some interference with activity (2)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'Some interference with activity (2)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:55', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'None (0)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:48:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'None (0)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-05T21:49:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered 'No (N)'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-05T21:49:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a24346ba-4af1-4c9e-a974-feb8bc829bc0'	System	06 Oct 2020 02:49:22
User entered '05 Oct 2020 21:49'	System	06 Oct 2020 02:49:22

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 5'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:55:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'No interference with activity (1)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:54:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'Some interference with activity (2)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:54:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'Some interference with activity (2)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:54:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'Some interference with activity (2)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:55:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'None (0)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:55:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'None (0)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-06T23:55:22', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered 'No (N)'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-06T23:56:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97b1ac3a-7e0c-4a3c-98cd-f496635bad03'	System	07 Oct 2020 04:56:07
User entered '06 Oct 2020 23:56'	System	07 Oct 2020 04:56:07

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 6'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:36:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:36:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'Some interference with activity (2)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:36:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'Significant; prevents daily activity (3)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:37:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'Significant; prevents daily activity (3)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:37:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:37:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'None (0)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-07T21:37:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered 'No (N)'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-07T21:37:33', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0ff4b3dc-3758-4c26-9957-47d097c4b44d'	System	08 Oct 2020 02:37:40
User entered '07 Oct 2020 21:37'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 16:02:18
User entered 'Day 7'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'No interference with activity (1)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'Some interference with activity (2)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'Some interference with activity (2)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:45:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'Some interference with activity (2)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:46:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:46:08', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'None (0)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-08T22:46:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered 'No (N)'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-08T22:46:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'df402199-6557-4c37-aced-16f170ba27b0'	System	09 Oct 2020 03:46:20
User entered '08 Oct 2020 22:46'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 16:02:18

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:37:40
User entered 'Day 8'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:20:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '225cacd7-930e-4409-a092-6b92babf8aa4'	System	10 Oct 2020 04:20:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:20:29', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '225cacd7-930e-4409-a092-6b92babf8aa4'	System	10 Oct 2020 04:20:36
User entered '09 Oct 2020 23:20'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:46:20
User entered 'Day 9'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:07:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8519e604-0fc5-4229-878d-675ee3cab0ea'	System	11 Oct 2020 03:08:05
User entered 'No interference with activity (1)'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8519e604-0fc5-4229-878d-675ee3cab0ea' User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:05
	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 04:20:36
User entered 'Day 10'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a6a93bbc-6a1d-43d2-97d9-ee76baa14b9a'	System	12 Oct 2020 02:20:44
User entered 'No interference with activity (1)'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a6a93bbc-6a1d-43d2-97d9-ee76baa14b9a'	System	12 Oct 2020 02:20:44
User entered '11 Oct 2020 21:20'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:08:05
User entered 'Day 11'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:54:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ac9b3d67-54ff-4f41-8b8e-7bf03d597bfd'	System	13 Oct 2020 00:54:46
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:54:46

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:54:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ac9b3d67-54ff-4f41-8b8e-7bf03d597bfd'	System	13 Oct 2020 00:54:46
User entered '12 Oct 2020 19:54'	System	13 Oct 2020 00:54:46

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 02:20:44
User entered 'Day 12'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'afaa6473-1b38-4a13-ac97-4d6def2be5b0'	System	14 Oct 2020 00:26:29
User entered 'None (0)'	System	14 Oct 2020 00:26:29

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:22', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'afaa6473-1b38-4a13-ac97-4d6def2be5b0'	System	14 Oct 2020 00:26:29
User entered '13 Oct 2020 19:26'	System	14 Oct 2020 00:26:29

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:37:40
User entered 'Day 8'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:20:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1d8960dc-67dc-42a2-9507-d5cdd4f1e77b'	System	10 Oct 2020 04:20:45
User entered 'Some interference with activity (2)'	System	10 Oct 2020 04:20:45

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:20:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1d8960dc-67dc-42a2-9507-d5cdd4f1e77b'	System	10 Oct 2020 04:20:45
User entered '09 Oct 2020 23:20'	System	10 Oct 2020 04:20:45

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:46:20
User entered 'Day 9'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'd06b9ed8-67e0-4d1b-b688-08dd40c8e718'	System	11 Oct 2020 03:08:12
User entered 'No interference with activity (1)'	System	11 Oct 2020 03:08:12

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'd06b9ed8-67e0-4d1b-b688-08dd40c8e718'	System	11 Oct 2020 03:08:12
User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:12

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 04:20:45
User entered 'Day 10'	System	10 Oct 2020 04:20:45

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:45', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b87a633-841c-45ab-9484-8e0d14c7b027'	System	12 Oct 2020 02:20:50
User entered 'No interference with activity (1)'	System	12 Oct 2020 02:20:50

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b87a633-841c-45ab-9484-8e0d14c7b027'	System	12 Oct 2020 02:20:50
User entered '11 Oct 2020 21:20'	System	12 Oct 2020 02:20:50

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:20:45

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:20:45

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:08:12
User entered 'Day 11'	System	11 Oct 2020 03:08:12

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:54:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0061561a-fc34-4452-9ae6-97e0795e2d0e'	System	13 Oct 2020 00:54:52
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:54:52

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:54:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0061561a-fc34-4452-9ae6-97e0795e2d0e'	System	13 Oct 2020 00:54:52
User entered '12 Oct 2020 19:54'	System	13 Oct 2020 00:54:52

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:08:12

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:08:12

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 02:20:50
User entered 'Day 12'	System	12 Oct 2020 02:20:50

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '66f57040-ece1-43ad-9f36-21b0c34c6d53'	System	14 Oct 2020 00:26:31
User entered 'No interference with activity (1)'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '66f57040-ece1-43ad-9f36-21b0c34c6d53'	System	14 Oct 2020 00:26:31
User entered '13 Oct 2020 19:26'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 02:20:50

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 02:20:50

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:54:52
User entered 'Day 13'	System	13 Oct 2020 00:54:52

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:12', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '01228b89-5a99-44a3-939a-e1ef295684d9'	System	14 Oct 2020 18:43:18
User entered 'No interference with activity (1)'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:14', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '01228b89-5a99-44a3-939a-e1ef295684d9'	System	14 Oct 2020 18:43:18
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:54:52

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:54:52

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:26:31
User entered 'Day 14'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:22:45', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9c9333a0-7ab9-4e5d-948c-4e33d7b98357'	System	15 Oct 2020 19:22:54
User entered 'Some interference with activity (2)'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:22:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9c9333a0-7ab9-4e5d-948c-4e33d7b98357'	System	15 Oct 2020 19:22:54
User entered '15 Oct 2020 14:22'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:43:18
User entered 'Day 15'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:52:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '424c6365-2550-48ec-aa3a-59a52bed2760'	System	17 Oct 2020 01:52:59
User entered 'No interference with activity (1)'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:52:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '424c6365-2550-48ec-aa3a-59a52bed2760'	System	17 Oct 2020 01:52:59
User entered '16 Oct 2020 20:52'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:22:54
User entered 'Day 16'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:27:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '39c0fc6c-2587-461f-b928-a555c13a181a'	System	18 Oct 2020 02:28:01
User entered 'No interference with activity (1)'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:27:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '39c0fc6c-2587-461f-b928-a555c13a181a'	System	18 Oct 2020 02:28:01
User entered '17 Oct 2020 21:27'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 01:52:59
User entered 'Day 17'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:58:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '835a8442-8ec2-427b-b159-ae8611d0475b'	System	19 Oct 2020 00:59:05
User entered 'No interference with activity (1)'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '835a8442-8ec2-427b-b159-ae8611d0475b'	System	19 Oct 2020 00:59:05
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 02:28:01
User entered 'Day 18'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'acfcec5d-1e3d-465e-b360-6605d59408ca'	System	20 Oct 2020 01:00:48
User entered 'No interference with activity (1)'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'acfcec5d-1e3d-465e-b360-6605d59408ca'	System	20 Oct 2020 01:00:48
User entered '19 Oct 2020 20:00'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 00:59:05
User entered 'Day 19'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f9a0dd40-105d-4a02-84c8-4ddacf508e90'	System	20 Oct 2020 18:44:48
User entered 'No interference with activity (1)'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f9a0dd40-105d-4a02-84c8-4ddacf508e90'	System	20 Oct 2020 18:44:48
User entered '20 Oct 2020 13:44'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:00:48
User entered 'Day 20'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:34:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b2290f14-4b40-4978-9f2d-d3574c8dacdb'	System	22 Oct 2020 15:34:56
User entered 'No interference with activity (1)'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:34:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b2290f14-4b40-4978-9f2d-d3574c8dacdb'	System	22 Oct 2020 15:34:56
User entered '22 Oct 2020 10:34'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:44:48
User entered 'Day 21'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3822bf10-0179-422f-817a-fa5a76adb103'	System	23 Oct 2020 02:02:15
User entered 'No interference with activity (1)'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3822bf10-0179-422f-817a-fa5a76adb103'	System	23 Oct 2020 02:02:15
User entered '22 Oct 2020 21:02'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 15:34:56
User entered 'Day 22'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '22696de8-586d-4826-b979-bd0101c14548'	System	24 Oct 2020 01:07:28
User entered 'No interference with activity (1)'	System	24 Oct 2020 01:07:28

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '22696de8-586d-4826-b979-bd0101c14548'	System	24 Oct 2020 01:07:28
User entered '23 Oct 2020 20:07'	System	24 Oct 2020 01:07:28

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 02:02:15
User entered 'Day 23'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:07:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be770eb8-ab7c-4154-bc61-2ac066e98483'	System	24 Oct 2020 18:07:56
User entered 'No interference with activity (1)'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:07:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be770eb8-ab7c-4154-bc61-2ac066e98483'	System	24 Oct 2020 18:07:56
User entered '24 Oct 2020 13:07'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 01:07:28
User entered 'Day 24'	System	24 Oct 2020 01:07:28

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:29', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '988e5623-2d6b-45b8-8f15-f722b1312c95'	System	25 Oct 2020 17:22:37
User entered 'No interference with activity (1)'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '988e5623-2d6b-45b8-8f15-f722b1312c95'	System	25 Oct 2020 17:22:37
User entered '25 Oct 2020 12:22'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:07:28

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:07:28

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 18:07:56
User entered 'Day 25'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a4132733-8af3-4df3-8dbf-04aafb72512f'	System	26 Oct 2020 17:34:48
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a4132733-8af3-4df3-8dbf-04aafb72512f'	System	26 Oct 2020 17:34:48
User entered '26 Oct 2020 12:34'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:22:37
User entered 'Day 26'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:34:48
User entered 'Day 27'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:37:40
User entered 'Day 8'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-09T23:20:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a471108b-1937-4eb9-ae85-54c2c7b6050b'	System	10 Oct 2020 04:20:56
User entered 'Significant; prevents daily activity (3)'	System	10 Oct 2020 04:20:56

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:20:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a471108b-1937-4eb9-ae85-54c2c7b6050b'	System	10 Oct 2020 04:20:56
User entered '09 Oct 2020 23:20'	System	10 Oct 2020 04:20:56

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:46:20
User entered 'Day 9'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:14', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '59ecd69c-9c8b-4e83-8618-49bb00deabd0'	System	11 Oct 2020 03:08:19
User entered 'Some interference with activity (2)'	System	11 Oct 2020 03:08:19

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:17', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '59ecd69c-9c8b-4e83-8618-49bb00deabd0'	System	11 Oct 2020 03:08:19
User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:19

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 04:20:56
User entered 'Day 10'	System	10 Oct 2020 04:20:56

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'aac1a1f6-8633-4472-8ea0-b69fdf531548'	System	12 Oct 2020 02:20:57
User entered 'No interference with activity (1)'	System	12 Oct 2020 02:20:57

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'aac1a1f6-8633-4472-8ea0-b69fdf531548'	System	12 Oct 2020 02:20:57
User entered '11 Oct 2020 21:20'	System	12 Oct 2020 02:20:57

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:20:56

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:20:56

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:08:19
User entered 'Day 11'	System	11 Oct 2020 03:08:19

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-12T19:54:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6e172ea0-35e3-4a0c-a87c-ac5da53f01a7'	System	13 Oct 2020 00:55:01
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:55:01

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:54:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6e172ea0-35e3-4a0c-a87c-ac5da53f01a7'	System	13 Oct 2020 00:55:01
User entered '12 Oct 2020 19:54'	System	13 Oct 2020 00:55:01

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:08:19

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:08:19

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 02:20:57
User entered 'Day 12'	System	12 Oct 2020 02:20:57

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:33', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '31a0babd-e005-4fdb-bc31-91a19d868e37'	System	14 Oct 2020 00:26:39
User entered 'No interference with activity (1)'	System	14 Oct 2020 00:26:39

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '31a0babd-e005-4fdb-bc31-91a19d868e37'	System	14 Oct 2020 00:26:39
User entered '13 Oct 2020 19:26'	System	14 Oct 2020 00:26:39

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 02:20:57

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 02:20:57

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:55:01
User entered 'Day 13'	System	13 Oct 2020 00:55:01

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '077fbc4f-a41e-498d-85d7-de7b65b9305b'	System	14 Oct 2020 18:43:24
User entered 'Some interference with activity (2)'	System	14 Oct 2020 18:43:24

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '077fbc4f-a41e-498d-85d7-de7b65b9305b'	System	14 Oct 2020 18:43:24
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 18:43:24

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:55:01

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:55:01

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:26:39
User entered 'Day 14'	System	14 Oct 2020 00:26:39

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-15T14:22:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'af8763aa-e91b-461e-8e61-8ae6ad6ef5ded'	System	15 Oct 2020 19:22:58
User entered 'Some interference with activity (2)'	System	15 Oct 2020 19:22:58

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:22:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'af8763aa-e91b-461e-8e61-8ae6ef5ded'	System	15 Oct 2020 19:22:58
User entered '15 Oct 2020 14:22'	System	15 Oct 2020 19:22:58

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:26:39

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:26:39

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:43:24
User entered 'Day 15'	System	14 Oct 2020 18:43:24

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-16T20:52:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c270b7cc-aa7f-4dff-adaf-26807d789743'	System	17 Oct 2020 01:53:06
User entered 'No interference with activity (1)'	System	17 Oct 2020 01:53:06

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c270b7cc-aa7f-4dff-adaf-26807d789743'	System	17 Oct 2020 01:53:06
User entered '16 Oct 2020 20:53'	System	17 Oct 2020 01:53:06

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:43:24

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:43:24

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:22:58
User entered 'Day 16'	System	15 Oct 2020 19:22:58

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-17T21:27:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a99bda15-2519-4240-8c5d-41e9b1e59704'	System	18 Oct 2020 02:28:07
User entered 'No interference with activity (1)'	System	18 Oct 2020 02:28:07

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a99bda15-2519-4240-8c5d-41e9b1e59704'	System	18 Oct 2020 02:28:07
User entered '17 Oct 2020 21:28'	System	18 Oct 2020 02:28:07

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:22:58

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:22:58

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 01:53:06
User entered 'Day 17'	System	17 Oct 2020 01:53:06

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ced056aa-e79d-4c7b-81b8-058bcb18161f'	System	19 Oct 2020 00:59:10
User entered 'No interference with activity (1)'	System	19 Oct 2020 00:59:10

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:06', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ced056aa-e79d-4c7b-81b8-058bcb18161f'	System	19 Oct 2020 00:59:10
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:10

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:53:06

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:53:06

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 02:28:07
User entered 'Day 18'	System	18 Oct 2020 02:28:07

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'e9298d9f-ec40-4ed7-84ec-8171259f38ee'	System	20 Oct 2020 01:01:14
User entered 'No interference with activity (1)'	System	20 Oct 2020 01:01:14

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'e9298d9f-ec40-4ed7-84ec-8171259f38ee'	System	20 Oct 2020 01:01:14
User entered '19 Oct 2020 20:00'	System	20 Oct 2020 01:01:14

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 02:28:07

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 02:28:07

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 00:59:10
User entered 'Day 19'	System	19 Oct 2020 00:59:10

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e9ab8bf-d89a-439d-8d7e-db70d7b23f68'	System	20 Oct 2020 18:44:55
User entered 'No interference with activity (1)'	System	20 Oct 2020 18:44:55

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e9ab8bf-d89a-439d-8d7e-db70d7b23f68'	System	20 Oct 2020 18:44:55
User entered '20 Oct 2020 13:44'	System	20 Oct 2020 18:44:55

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 00:59:10

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 00:59:10

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:01:14
User entered 'Day 20'	System	20 Oct 2020 01:01:14

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-22T10:34:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4d42d2a6-a407-4d88-a413-248e12fc8756'	System	22 Oct 2020 15:35:05
User entered 'No interference with activity (1)'	System	22 Oct 2020 15:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4d42d2a6-a407-4d88-a413-248e12fc8756'	System	22 Oct 2020 15:35:05
User entered '22 Oct 2020 10:35'	System	22 Oct 2020 15:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:01:14

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:01:14

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:44:55
User entered 'Day 21'	System	20 Oct 2020 18:44:55

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '29e4a9c5-5add-41de-b6c4-b1fc8925bb84'	System	23 Oct 2020 02:02:23
User entered 'No interference with activity (1)'	System	23 Oct 2020 02:02:23

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '29e4a9c5-5add-41de-b6c4-b1fc8925bb84'	System	23 Oct 2020 02:02:23
User entered '22 Oct 2020 21:02'	System	23 Oct 2020 02:02:23

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:44:55

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:44:55

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 15:35:05
User entered 'Day 22'	System	22 Oct 2020 15:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:06', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a1c44d5e-148d-4656-b6de-d64b8c88b2e1'	System	24 Oct 2020 01:07:22
User entered 'No interference with activity (1)'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a1c44d5e-148d-4656-b6de-d64b8c88b2e1'	System	24 Oct 2020 01:07:22
User entered '23 Oct 2020 20:07'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 15:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 15:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 02:02:23
User entered 'Day 23'	System	23 Oct 2020 02:02:23

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-24T13:07:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dbc69cb4-6c8c-4422-959f-adb3f88d5df7'	System	24 Oct 2020 18:08:05
User entered 'No interference with activity (1)'	System	24 Oct 2020 18:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:07:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'dbc69cb4-6c8c-4422-959f-adb3f88d5df7'	System	24 Oct 2020 18:08:05
User entered '24 Oct 2020 13:07'	System	24 Oct 2020 18:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 02:02:23

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 02:02:23

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 01:07:22
User entered 'Day 24'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:34', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ca456ffe-d4a4-4db6-9123-9eb3e2b21717'	System	25 Oct 2020 17:22:42
User entered 'No interference with activity (1)'	System	25 Oct 2020 17:22:42

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:37', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ca456ffe-d4a4-4db6-9123-9eb3e2b21717'	System	25 Oct 2020 17:22:42
User entered '25 Oct 2020 12:22'	System	25 Oct 2020 17:22:42

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 18:08:05
User entered 'Day 25'	System	24 Oct 2020 18:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '7d580a80-4cea-4301-b673-caf2c4a8ab04'	System	26 Oct 2020 17:34:54
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:34:54

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '7d580a80-4cea-4301-b673-caf2c4a8ab04'	System	26 Oct 2020 17:34:54
User entered '26 Oct 2020 12:34'	System	26 Oct 2020 17:34:54

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 18:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 18:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:22:42
User entered 'Day 26'	System	25 Oct 2020 17:22:42

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:22:42

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:22:42

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:34:54
User entered 'Day 27'	System	26 Oct 2020 17:34:54

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:34:54

US3252602

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:34:54

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:37:40
User entered 'Day 8'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:21:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c88d82fb-c342-49b1-ba20-9f3993424f7e'	System	10 Oct 2020 04:21:08
User entered 'Some interference with activity (2)'	System	10 Oct 2020 04:21:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:21:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c88d82fb-c342-49b1-ba20-9f3993424f7e'	System	10 Oct 2020 04:21:08
User entered '09 Oct 2020 23:21'	System	10 Oct 2020 04:21:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:46:20
User entered 'Day 9'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:24', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ca6a21b5-8ae5-498b-a479-3e1aa9c93486'	System	11 Oct 2020 03:08:29
User entered 'Some interference with activity (2)'	System	11 Oct 2020 03:08:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:27', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ca6a21b5-8ae5-498b-a479-3e1aa9c93486'	System	11 Oct 2020 03:08:29
User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 04:21:08
User entered 'Day 10'	System	10 Oct 2020 04:21:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:20:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '060cb961-a09f-4606-a91b-c64446b8eab4'	System	12 Oct 2020 02:21:04
User entered 'Some interference with activity (2)'	System	12 Oct 2020 02:21:04

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:21:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '060cb961-a09f-4606-a91b-c64446b8eab4'	System	12 Oct 2020 02:21:04
User entered '11 Oct 2020 21:21'	System	12 Oct 2020 02:21:04

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:21:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:21:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:08:29
User entered 'Day 11'	System	11 Oct 2020 03:08:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:55:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cea609ae-6792-4978-8e80-a605cee2bb9a'	System	13 Oct 2020 00:55:08
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:55:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:55:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cea609ae-6792-4978-8e80-a605cee2bb9a'	System	13 Oct 2020 00:55:08
User entered '12 Oct 2020 19:55'	System	13 Oct 2020 00:55:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:08:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:08:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 02:21:04
User entered 'Day 12'	System	12 Oct 2020 02:21:04

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9e502d3d-8e23-4871-9174-41a47a7c8eab'	System	14 Oct 2020 00:26:51
User entered 'No interference with activity (1)'	System	14 Oct 2020 00:26:51

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9e502d3d-8e23-4871-9174-41a47a7c8eab'	System	14 Oct 2020 00:26:51
User entered '13 Oct 2020 19:26'	System	14 Oct 2020 00:26:51

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 02:21:04

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 02:21:04

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:55:08
User entered 'Day 13'	System	13 Oct 2020 00:55:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'd8f55f21-8df8-47d6-913e-550ac8a36691'	System	14 Oct 2020 18:43:35
User entered 'Some interference with activity (2)'	System	14 Oct 2020 18:43:35

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'd8f55f21-8df8-47d6-913e-550ac8a36691'	System	14 Oct 2020 18:43:35
User entered '14 Oct 2020 13:43'	System	14 Oct 2020 18:43:35

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:55:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:55:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:26:51
User entered 'Day 14'	System	14 Oct 2020 00:26:51

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:22:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'e5aaaaa6-6d61-478b-9aa0-3eb1f069924e'	System	15 Oct 2020 19:23:10
User entered 'Some interference with activity (2)'	System	15 Oct 2020 19:23:10

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:22:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'e5aaaaa6-6d61-478b-9aa0-3eb1f069924e'	System	15 Oct 2020 19:23:10
User entered '15 Oct 2020 14:22'	System	15 Oct 2020 19:23:10

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:26:51

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:26:51

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:43:35
User entered 'Day 15'	System	14 Oct 2020 18:43:35

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:06', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6a566e61-66ad-4bec-9b70-23dfbf97a808'	System	17 Oct 2020 01:53:12
User entered 'No interference with activity (1)'	System	17 Oct 2020 01:53:12

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:08', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6a566e61-66ad-4bec-9b70-23dfbf97a808'	System	17 Oct 2020 01:53:12
User entered '16 Oct 2020 20:53'	System	17 Oct 2020 01:53:12

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:43:35

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:43:35

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:23:10
User entered 'Day 16'	System	15 Oct 2020 19:23:10

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f89035b4-7209-4d3d-9eb2-b6ac48c0f274'	System	18 Oct 2020 02:28:09
User entered 'No interference with activity (1)'	System	18 Oct 2020 02:28:09

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f89035b4-7209-4d3d-9eb2-b6ac48c0f274'	System	18 Oct 2020 02:28:09
User entered '17 Oct 2020 21:28'	System	18 Oct 2020 02:28:09

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:23:10

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:23:10

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 01:53:12
User entered 'Day 17'	System	17 Oct 2020 01:53:12

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'daae501a-81d2-43fe-ad20-23e12d5fb32d'	System	19 Oct 2020 00:59:17
User entered 'No interference with activity (1)'	System	19 Oct 2020 00:59:17

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'daae501a-81d2-43fe-ad20-23e12d5fb32d'	System	19 Oct 2020 00:59:17
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:17

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:53:12

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:53:12

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 02:28:09
User entered 'Day 18'	System	18 Oct 2020 02:28:09

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be286129-2bb2-4f84-8f9e-dff8c1c9f9a7'	System	20 Oct 2020 01:01:18
User entered 'No interference with activity (1)'	System	20 Oct 2020 01:01:18

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:55', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be286129-2bb2-4f84-8f9e-dff8c1c9f9a7'	System	20 Oct 2020 01:01:18
User entered '19 Oct 2020 20:00'	System	20 Oct 2020 01:01:18

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 02:28:09

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 02:28:09

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 00:59:17
User entered 'Day 19'	System	19 Oct 2020 00:59:17

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b92d7c4f-6e8a-493a-9214-5fc88d9a1588'	System	20 Oct 2020 18:45:02
User entered 'No interference with activity (1)'	System	20 Oct 2020 18:45:02

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b92d7c4f-6e8a-493a-9214-5fc88d9a1588' User entered '20 Oct 2020 13:44'	System	20 Oct 2020 18:45:02

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 00:59:17

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 00:59:17

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:01:18
User entered 'Day 20'	System	20 Oct 2020 01:01:18

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef2436cd-b5c3-420c-82cf-31a05cf6916e'	System	22 Oct 2020 15:35:11
User entered 'No interference with activity (1)'	System	22 Oct 2020 15:35:11

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:06', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef2436cd-b5c3-420c-82cf-31a05cf6916e'	System	22 Oct 2020 15:35:11
User entered '22 Oct 2020 10:35'	System	22 Oct 2020 15:35:11

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:01:18

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:01:18

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:45:02
User entered 'Day 21'	System	20 Oct 2020 18:45:02

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'aaf1bc19-8a45-4b5c-84d5-b6741807935a'	System	23 Oct 2020 02:02:29
User entered 'No interference with activity (1)'	System	23 Oct 2020 02:02:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:24', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'aaf1bc19-8a45-4b5c-84d5-b6741807935a'	System	23 Oct 2020 02:02:29
User entered '22 Oct 2020 21:02'	System	23 Oct 2020 02:02:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:45:02

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:45:02

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 15:35:11
User entered 'Day 22'	System	22 Oct 2020 15:35:11

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'e4337f8f-08be-4ebf-a401-51f8a3817cb5'	System	24 Oct 2020 01:07:24
User entered 'No interference with activity (1)'	System	24 Oct 2020 01:07:24

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'e4337f8f-08be-4ebf-a401-51f8a3817cb5'	System	24 Oct 2020 01:07:24
User entered '23 Oct 2020 20:07'	System	24 Oct 2020 01:07:24

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 15:35:11

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 15:35:11

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 02:02:29
User entered 'Day 23'	System	23 Oct 2020 02:02:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:08:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97041b2a-1cdc-4946-8c24-9d831753ce75'	System	24 Oct 2020 18:08:08
User entered 'No interference with activity (1)'	System	24 Oct 2020 18:08:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:08:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '97041b2a-1cdc-4946-8c24-9d831753ce75'	System	24 Oct 2020 18:08:08
User entered '24 Oct 2020 13:08'	System	24 Oct 2020 18:08:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 02:02:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 02:02:29

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 01:07:24
User entered 'Day 24'	System	24 Oct 2020 01:07:24

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '790dec0d-7d84-4045-9a58-c87ba3f0a4c9'	System	25 Oct 2020 17:22:50
User entered 'No interference with activity (1)'	System	25 Oct 2020 17:22:50

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:44', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '790dec0d-7d84-4045-9a58-c87ba3f0a4c9'	System	25 Oct 2020 17:22:50
User entered '25 Oct 2020 12:22'	System	25 Oct 2020 17:22:50

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:07:24

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:07:24

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 18:08:08
User entered 'Day 25'	System	24 Oct 2020 18:08:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6d02a5d4-210d-46f9-8746-65e72dad0b15'	System	26 Oct 2020 17:35:00
User entered 'No interference with activity (1)'	System	26 Oct 2020 17:35:00

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6d02a5d4-210d-46f9-8746-65e72dad0b15'	System	26 Oct 2020 17:35:00
User entered '26 Oct 2020 12:34'	System	26 Oct 2020 17:35:00

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 18:08:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 18:08:08

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:22:50
User entered 'Day 26'	System	25 Oct 2020 17:22:50

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:22:50

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:22:50

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:35:00
User entered 'Day 27'	System	26 Oct 2020 17:35:00

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:35:00

US3252602

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:35:00

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:37:40
User entered 'Day 8'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:21:12', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ae76e1ce-ad26-4642-a706-5ed54092dabf'	System	10 Oct 2020 04:21:33
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Oct 2020 04:21:33

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:21:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ae76e1ce-ad26-4642-a706-5ed54092dabf'	System	10 Oct 2020 04:21:33
User entered '09 Oct 2020 23:21'	System	10 Oct 2020 04:21:33

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:37:40

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:46:20
User entered 'Day 9'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:53:09

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57c37639-2f3f-4370-a995-7d7914cb687e'	System	11 Oct 2020 03:08:37
User entered 'None (0)'	System	11 Oct 2020 03:08:37

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:33', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57c37639-2f3f-4370-a995-7d7914cb687e'	System	11 Oct 2020 03:08:37
User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:37

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:46:20

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:36:31
User entered 'Day 8'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-09T23:21:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '7cab07d0-153b-4223-a1e3-a3489ae20b08'	System	10 Oct 2020 04:21:45
User entered 'No (N)'	System	10 Oct 2020 04:21:45

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:21:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '7cab07d0-153b-4223-a1e3-a3489ae20b08'	System	10 Oct 2020 04:21:45
User entered '09 Oct 2020 23:21'	System	10 Oct 2020 04:21:45

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:45:44
User entered 'Day 9'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:37', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '62822132-a10e-458a-b52d-9c8462780da4'	System	11 Oct 2020 03:08:43
User entered 'No (N)'	System	11 Oct 2020 03:08:43

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '62822132-a10e-458a-b52d-9c8462780da4'	System	11 Oct 2020 03:08:43
User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:43

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 04:20:36
User entered 'Day 10'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-11T21:21:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9ab8154e-ae7e-4b68-9c43-06737d8f9a32'	System	12 Oct 2020 02:21:09
User entered 'No (N)'	System	12 Oct 2020 02:21:09

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:21:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9ab8154e-ae7e-4b68-9c43-06737d8f9a32'	System	12 Oct 2020 02:21:09
User entered '11 Oct 2020 21:21'	System	12 Oct 2020 02:21:09

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:20:36

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:08:05
User entered 'Day 11'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-12T19:55:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0645cac8-bc62-49c7-9805-0e2f38af12c2'	System	13 Oct 2020 00:55:13
User entered 'No (N)'	System	13 Oct 2020 00:55:13

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:55:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '0645cac8-bc62-49c7-9805-0e2f38af12c2'	System	13 Oct 2020 00:55:13
User entered '12 Oct 2020 19:55'	System	13 Oct 2020 00:55:13

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:08:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 02:20:44
User entered 'Day 12'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b7eb193-7b9b-4968-818f-c6c5cd37141e'	System	14 Oct 2020 00:26:58
User entered 'No (N)'	System	14 Oct 2020 00:26:58

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:26:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b7eb193-7b9b-4968-818f-c6c5cd37141e'	System	14 Oct 2020 00:26:58
User entered '13 Oct 2020 19:26'	System	14 Oct 2020 00:26:58

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 02:20:44

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:54:46
User entered 'Day 13'	System	13 Oct 2020 00:54:46

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:32', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '70ea6028-1314-43d2-af0b-d23994c3265f'	System	14 Oct 2020 18:43:42
User entered 'No (N)'	System	14 Oct 2020 18:43:42

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '70ea6028-1314-43d2-af0b-d23994c3265f' User entered '14 Oct 2020 13:43'	System	14 Oct 2020 18:43:42

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:54:46

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:54:46

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:26:31
User entered 'Day 14'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-15T14:23:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '69737423-22a1-46a6-8d62-394b84dc655d'	System	15 Oct 2020 19:23:11
User entered 'No (N)'	System	15 Oct 2020 19:23:11

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:23:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '69737423-22a1-46a6-8d62-394b84dc655d' User entered '15 Oct 2020 14:23'	System	15 Oct 2020 19:23:11

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:26:31

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:43:18
User entered 'Day 15'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8e3221dd-dba2-44e3-a51d-c1da201dcc96'	System	17 Oct 2020 01:53:19
User entered 'No (N)'	System	17 Oct 2020 01:53:19

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8e3221dd-dba2-44e3-a51d-c1da201dcc96'	System	17 Oct 2020 01:53:19
User entered '16 Oct 2020 20:53'	System	17 Oct 2020 01:53:19

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:43:18

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:22:54
User entered 'Day 16'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:08', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4a120537-6592-4618-a11c-dc275172474f'	System	18 Oct 2020 02:28:18
User entered 'No (N)'	System	18 Oct 2020 02:28:18

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4a120537-6592-4618-a11c-dc275172474f'	System	18 Oct 2020 02:28:18
User entered '17 Oct 2020 21:28'	System	18 Oct 2020 02:28:18

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 01:52:59
User entered 'Day 17'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:14', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b2ef9e46-4640-414b-9537-c780605eddb0'	System	19 Oct 2020 00:59:23
User entered 'No (N)'	System	19 Oct 2020 00:59:23

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b2ef9e46-4640-414b-9537-c780605eddb0'	System	19 Oct 2020 00:59:23
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:23

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:52:59

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 02:28:01
User entered 'Day 18'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-19T20:00:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '01e21221-49e2-476e-8771-943824cec2a2'	System	20 Oct 2020 01:01:45
User entered 'No (N)'	System	20 Oct 2020 01:01:45

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:01:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '01e21221-49e2-476e-8771-943824cec2a2'	System	20 Oct 2020 01:01:45
User entered '19 Oct 2020 20:01'	System	20 Oct 2020 01:01:45

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 02:28:01

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 00:59:05
User entered 'Day 19'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6b1e5ec6-d73a-49e9-b6e9-bd3911d2563e'	System	20 Oct 2020 18:45:07
User entered 'No (N)'	System	20 Oct 2020 18:45:07

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:44:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6b1e5ec6-d73a-49e9-b6e9-bd3911d2563e' User entered '20 Oct 2020 13:44'	System	20 Oct 2020 18:45:07
	System	20 Oct 2020 18:45:07

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 00:59:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:00:48
User entered 'Day 20'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'aaa0e02b-3b96-4a00-9504-cc6bb5fba6aa'	System	22 Oct 2020 15:35:17
User entered 'No (N)'	System	22 Oct 2020 15:35:17

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:12', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'aaa0e02b-3b96-4a00-9504-cc6bb5fba6aa'	System	22 Oct 2020 15:35:17
User entered '22 Oct 2020 10:35'	System	22 Oct 2020 15:35:17

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:00:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:44:48
User entered 'Day 21'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '67166ef4-e2f4-42a9-8e2f-33554022dea5'	System	23 Oct 2020 02:02:39
User entered 'No (N)'	System	23 Oct 2020 02:02:39

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '67166ef4-e2f4-42a9-8e2f-33554022dea5'	System	23 Oct 2020 02:02:39
User entered '22 Oct 2020 21:02'	System	23 Oct 2020 02:02:39

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:44:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 15:34:56
User entered 'Day 22'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b3c3e5b3-f1f8-4317-830e-65a85f7c9e9c'	System	24 Oct 2020 01:07:25
User entered 'No (N)'	System	24 Oct 2020 01:07:25

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b3c3e5b3-f1f8-4317-830e-65a85f7c9e9c'	System	24 Oct 2020 01:07:25
User entered '23 Oct 2020 20:07'	System	24 Oct 2020 01:07:25

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 15:34:56

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 02:02:15
User entered 'Day 23'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-24T13:08:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '138ec2de-74ab-4034-9d98-193a9dda65c8'	System	24 Oct 2020 18:08:11
User entered 'No (N)'	System	24 Oct 2020 18:08:11

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:08:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '138ec2de-74ab-4034-9d98-193a9dda65c8'	System	24 Oct 2020 18:08:11
User entered '24 Oct 2020 13:08'	System	24 Oct 2020 18:08:11

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 02:02:15

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 01:07:22
User entered 'Day 24'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6deae2d-0fe7-4a6b-b13b-225a9b50983b'	System	25 Oct 2020 17:22:54
User entered 'No (N)'	System	25 Oct 2020 17:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6deae2d-0fe7-4a6b-b13b-225a9b50983b'	System	25 Oct 2020 17:22:54
User entered '25 Oct 2020 12:22'	System	25 Oct 2020 17:22:54

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:07:22

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 18:07:56
User entered 'Day 25'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:56', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1df60384-be85-4ea1-afae-cd94dd389ed8'	System	26 Oct 2020 17:35:05
User entered 'No (N)'	System	26 Oct 2020 17:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:34:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1df60384-be85-4ea1-afae-cd94dd389ed8'	System	26 Oct 2020 17:35:05
User entered '26 Oct 2020 12:34'	System	26 Oct 2020 17:35:05

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 18:07:56

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:22:37
User entered 'Day 26'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:22:37

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:34:48
User entered 'Day 27'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:34:48

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 02:36:31
User entered 'Day 8'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-09T23:22:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'fd49226c-0759-4e79-987d-7fc6d8edcf9c'	System	10 Oct 2020 04:22:07
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	10 Oct 2020 04:22:07

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-09T23:22:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'fd49226c-0759-4e79-987d-7fc6d8edcf9c'	System	10 Oct 2020 04:22:07
User entered '09 Oct 2020 23:22'	System	10 Oct 2020 04:22:07

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:36:31

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 03:45:44
User entered 'Day 9'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '521ea42b-c193-4849-8b7e-ff856f0b3e2a'	System	11 Oct 2020 03:08:55
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 03:08:55

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-10T22:08:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '521ea42b-c193-4849-8b7e-ff856f0b3e2a'	System	11 Oct 2020 03:08:55
User entered '10 Oct 2020 22:08'	System	11 Oct 2020 03:08:55

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:45:44

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Oct 2020 04:22:07
User entered 'Day 10'	System	10 Oct 2020 04:22:07

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-11T21:21:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b584d3af-95df-427a-9469-d95fce061c23'	System	12 Oct 2020 02:21:20
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 02:21:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-11T21:21:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b584d3af-95df-427a-9469-d95fce061c23'	System	12 Oct 2020 02:21:20
User entered '11 Oct 2020 21:21'	System	12 Oct 2020 02:21:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:22:07

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:22:07

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Oct 2020 03:08:55
User entered 'Day 11'	System	11 Oct 2020 03:08:55

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-12T19:55:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '7c80edbd-8947-465b-99bf-d968a982003e'	System	13 Oct 2020 00:55:20
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 00:55:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-12T19:55:17', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '7c80edbd-8947-465b-99bf-d968a982003e'	System	13 Oct 2020 00:55:20
User entered '12 Oct 2020 19:55'	System	13 Oct 2020 00:55:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:08:55

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:08:55

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Oct 2020 02:21:20
User entered 'Day 12'	System	12 Oct 2020 02:21:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-13T19:27:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'fd010a43-91ed-495e-8658-a719d0e1df11'	System	14 Oct 2020 00:27:09
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 00:27:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-13T19:27:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'fd010a43-91ed-495e-8658-a719d0e1df11'	System	14 Oct 2020 00:27:09
User entered '13 Oct 2020 19:27'	System	14 Oct 2020 00:27:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 02:21:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 02:21:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:55:20
User entered 'Day 13'	System	13 Oct 2020 00:55:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a2761d73-6004-4229-a333-e3f7916942cb'	System	14 Oct 2020 18:43:46
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 18:43:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-14T13:43:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a2761d73-6004-4229-a333-e3f7916942cb' User entered '14 Oct 2020 13:43'	System	14 Oct 2020 18:43:46
	System	14 Oct 2020 18:43:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:55:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(13)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:55:20

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 00:27:09
User entered 'Day 14'	System	14 Oct 2020 00:27:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-15T14:23:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '96268514-0e24-4a8c-8846-acc797b720ab'	System	15 Oct 2020 19:23:18
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 19:23:18

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-15T14:23:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '96268514-0e24-4a8c-8846-acc797b720ab' User entered '15 Oct 2020 14:23'	System	15 Oct 2020 19:23:18
	System	15 Oct 2020 19:23:18

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 00:27:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(14)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 00:27:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 18:43:46
User entered 'Day 15'	System	14 Oct 2020 18:43:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '12dd2895-e517-4b6a-9741-e92e27d4151b'	System	17 Oct 2020 01:53:26
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 01:53:26

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-16T20:53:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '12dd2895-e517-4b6a-9741-e92e27d4151b'	System	17 Oct 2020 01:53:26
User entered '16 Oct 2020 20:53'	System	17 Oct 2020 01:53:26

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 18:43:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(15)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 18:43:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 19:23:18
User entered 'Day 16'	System	15 Oct 2020 19:23:18

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:14', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a5e7b44b-bd4b-4f28-91d3-3d90de8da04b'	System	18 Oct 2020 02:28:23
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 02:28:23

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-17T21:28:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a5e7b44b-bd4b-4f28-91d3-3d90de8da04b'	System	18 Oct 2020 02:28:23
User entered '17 Oct 2020 21:28'	System	18 Oct 2020 02:28:23

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:23:18

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(16)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:23:18

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(17)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Oct 2020 01:53:26
User entered 'Day 17'	System	17 Oct 2020 01:53:26

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(17)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '79bfac96-69b2-4c3b-a78d-62d6c555d9ae'	System	19 Oct 2020 00:59:29
User entered 'Does not interfere with activity (2)'	System	19 Oct 2020 00:59:29

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-18T19:59:21', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '79bfac96-69b2-4c3b-a78d-62d6c555d9ae'	System	19 Oct 2020 00:59:29
User entered '18 Oct 2020 19:59'	System	19 Oct 2020 00:59:29

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	17 Oct 2020 01:53:26

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(17)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	17 Oct 2020 01:53:26

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(18)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Oct 2020 02:28:23
User entered 'Day 18'	System	18 Oct 2020 02:28:23

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(18)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-19T20:01:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4bf3cb55-c433-4f53-84e9-b60d46f445a2'	System	20 Oct 2020 01:01:46
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 01:01:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-19T20:01:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '4bf3cb55-c433-4f53-84e9-b60d46f445a2'	System	20 Oct 2020 01:01:46
User entered '19 Oct 2020 20:01'	System	20 Oct 2020 01:01:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	18 Oct 2020 02:28:23

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(18)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	18 Oct 2020 02:28:23

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(19)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Oct 2020 00:59:29
User entered 'Day 19'	System	19 Oct 2020 00:59:29

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(19)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-20T13:45:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f91ee8fc-49f7-4030-b2a4-b9b748ddc93a'	System	20 Oct 2020 18:45:21
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 18:45:21

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-20T13:45:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f91ee8fc-49f7-4030-b2a4-b9b748ddc93a'	System	20 Oct 2020 18:45:21
User entered '20 Oct 2020 13:45'	System	20 Oct 2020 18:45:21

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 00:59:29

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(19)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 00:59:29

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(20)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:01:46
User entered 'Day 20'	System	20 Oct 2020 01:01:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(20)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5ee03136-a2fb-461b-98d8-c2cb54f68fa8'	System	22 Oct 2020 15:35:24
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 15:35:24

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T10:35:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5ee03136-a2fb-461b-98d8-c2cb54f68fa8'	System	22 Oct 2020 15:35:24
User entered '22 Oct 2020 10:35'	System	22 Oct 2020 15:35:24

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 01:01:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(20)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 01:01:46

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(21)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 18:45:21
User entered 'Day 21'	System	20 Oct 2020 18:45:21

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(21)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '374f1fe3-bfc9-408e-a7fb-12117d3c52a9'	System	23 Oct 2020 02:02:43
User entered 'Does not interfere with activity (2)'	System	23 Oct 2020 02:02:43

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-22T21:02:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '374f1fe3-bfc9-408e-a7fb-12117d3c52a9'	System	23 Oct 2020 02:02:43
User entered '22 Oct 2020 21:02'	System	23 Oct 2020 02:02:43

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 18:45:21

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(21)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 18:45:21

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(22)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 15:35:24
User entered 'Day 22'	System	22 Oct 2020 15:35:24

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(22)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:24', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '89ddfe0c-ed0b-434e-9f39-81a52b8051cc'	System	24 Oct 2020 01:07:32
User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 01:07:32

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-23T20:07:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '89ddfe0c-ed0b-434e-9f39-81a52b8051cc'	System	24 Oct 2020 01:07:32
User entered '23 Oct 2020 20:07'	System	24 Oct 2020 01:07:32

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 15:35:24

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(22)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 15:35:24

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(23)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Oct 2020 02:02:43
User entered 'Day 23'	System	23 Oct 2020 02:02:43

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(23)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-24T13:08:11', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '819225ed-e006-4771-b618-950adf1c1258'	System	24 Oct 2020 18:08:17
User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 18:08:17

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-24T13:08:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '819225ed-e006-4771-b618-950adf1c1258'	System	24 Oct 2020 18:08:17
User entered '24 Oct 2020 13:08'	System	24 Oct 2020 18:08:17

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 02:02:43

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(23)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 02:02:43

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(24)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 01:07:32
User entered 'Day 24'	System	24 Oct 2020 01:07:32

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(24)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-25T12:22:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b02ea21c-0f0c-4209-94ff-ab7ddebeb0b8'	System	25 Oct 2020 17:23:06
User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 17:23:06

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-25T12:23:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b02ea21c-0f0c-4209-94ff-ab7ddebeb0b8'	System	25 Oct 2020 17:23:06
User entered '25 Oct 2020 12:23'	System	25 Oct 2020 17:23:06

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 01:07:32

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(24)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 01:07:32

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(25)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Oct 2020 18:08:17
User entered 'Day 25'	System	24 Oct 2020 18:08:17

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(25)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-26T12:35:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '76e43e1b-3c90-41a2-864d-6b514d65f0bc'	System	26 Oct 2020 17:35:09
User entered 'Does not interfere with activity (2)'	System	26 Oct 2020 17:35:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-26T12:35:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '76e43e1b-3c90-41a2-864d-6b514d65f0bc'	System	26 Oct 2020 17:35:09
User entered '26 Oct 2020 12:35'	System	26 Oct 2020 17:35:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	24 Oct 2020 18:08:17

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(25)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	24 Oct 2020 18:08:17

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(26)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Oct 2020 17:23:06
User entered 'Day 26'	System	25 Oct 2020 17:23:06

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 17:23:06

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(26)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 17:23:06

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(27)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Oct 2020 17:35:09
User entered 'Day 27'	System	26 Oct 2020 17:35:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 17:35:09

US3252602

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(27)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 17:35:09

US3252602

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	10 Oct 2020 20:33:03

US3252602

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	10 Oct 2020 20:33:03

US3252602

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	10 Oct 2020 20:33:03

US3252602

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	10 Oct 2020 20:33:03

US3252602

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	10 Oct 2020 20:33:26

US3252602

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Oct 2020 20:33:26

US3252602

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	17 Oct 2020 04:41:59

US3252602

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	17 Oct 2020 04:41:59

US3252602

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	17 Oct 2020 04:41:59

US3252602

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	17 Oct 2020 04:41:59

US3252602

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	17 Oct 2020 04:42:04

US3252602

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Oct 2020 04:42:04

US3252602

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	24 Oct 2020 02:33:13

US3252602

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	24 Oct 2020 02:33:13

US3252602

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	24 Oct 2020 02:33:13

US3252602

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	24 Oct 2020 02:33:13

US3252602

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	24 Oct 2020 02:33:18

US3252602

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Oct 2020 02:33:18

US3252602

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:34:58

US3252602

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:34:58

US3252602

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:34:58

US3252602

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:53:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	31 Oct 2020 03:34:58

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '09:18'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 09:18'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '16'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:53:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '10:16'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 10:16'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.0' F	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '16'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:53:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Oct 2020 03:36:59

US3252602

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:37:45

US3252602

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:53:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:37:45

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '09:46'	Joanna Gurrola (b) (4) (b) (4)	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 09:46'	System	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:53:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	30 Oct 2020 14:51:13

US3252602

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:22

US3252602

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:22

US3252602

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:37'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:22

US3252602

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 09:37'	System	31 Oct 2020 03:38:22

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:53:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:38'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '30 Oct 2020 09:38'	System	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 03:38:41

US3252602

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	31 Oct 2020 03:38:46

US3252602

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Oct 2020 03:38:46

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:12', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b805bd5-a926-4541-bb40-924832b2d309'	System	30 Oct 2020 15:20:39
User entered 'Yes (Y)'	System	30 Oct 2020 15:20:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:22', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b805bd5-a926-4541-bb40-924832b2d309'	System	30 Oct 2020 15:20:39
User entered '97.0'	System	30 Oct 2020 15:20:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b805bd5-a926-4541-bb40-924832b2d309'	System	30 Oct 2020 15:20:39
User entered 'No (N)'	System	30 Oct 2020 15:20:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:34', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9b805bd5-a926-4541-bb40-924832b2d309'	System	30 Oct 2020 15:20:39
User entered '30 Oct 2020 10:20'	System	30 Oct 2020 15:20:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 10:06'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:36'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:44:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f8ead620-13f1-49f5-a4ee-26e6ca1a977f'	System	30 Oct 2020 21:44:55
User entered 'No (N)'	System	30 Oct 2020 21:44:55

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:44:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f8ead620-13f1-49f5-a4ee-26e6ca1a977f'	System	30 Oct 2020 21:44:55
User entered 'No (N)'	System	30 Oct 2020 21:44:55

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:44:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f8ead620-13f1-49f5-a4ee-26e6ca1a977f'	System	30 Oct 2020 21:44:55
User entered '30 Oct 2020 16:44'	System	30 Oct 2020 21:44:55

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 13:31'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 2'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'affaf192-cba6-43c1-9a61-534278543a95'	System	01 Nov 2020 05:30:39
User entered 'Yes (Y)'	System	01 Nov 2020 05:30:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:27', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'affaf192-cba6-43c1-9a61-534278543a95'	System	01 Nov 2020 05:30:39
User entered '95.7'	System	01 Nov 2020 05:30:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:32', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'affaf192-cba6-43c1-9a61-534278543a95'	System	01 Nov 2020 05:30:39
User entered 'No (N)'	System	01 Nov 2020 05:30:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'affaf192-cba6-43c1-9a61-534278543a95'	System	01 Nov 2020 05:30:39
User entered '01 Nov 2020 00:30'	System	01 Nov 2020 05:30:39

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 3'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:08:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9ed3702d-3fa7-4554-a553-78d7bb541b9e'	System	02 Nov 2020 03:09:42
User entered 'Yes (Y)'	System	02 Nov 2020 03:09:42

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:33', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9ed3702d-3fa7-4554-a553-78d7bb541b9e'	System	02 Nov 2020 03:09:42
User entered '97.5'	System	02 Nov 2020 03:09:42

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:36', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9ed3702d-3fa7-4554-a553-78d7bb541b9e'	System	02 Nov 2020 03:09:42
User entered 'No (N)'	System	02 Nov 2020 03:09:42

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '9ed3702d-3fa7-4554-a553-78d7bb541b9e'	System	02 Nov 2020 03:09:42
User entered '01 Nov 2020 21:09'	System	02 Nov 2020 03:09:42

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 4'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:46:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f86d655e-cb8f-4a4d-8f74-b128ceaf2ec2'	System	03 Nov 2020 02:48:23
User entered 'Yes (Y)'	System	03 Nov 2020 02:48:23

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f86d655e-cb8f-4a4d-8f74-b128ceaf2ec2'	System	03 Nov 2020 02:48:23
User entered '96.1'	System	03 Nov 2020 02:48:23

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f86d655e-cb8f-4a4d-8f74-b128ceaf2ec2'	System	03 Nov 2020 02:48:23
User entered 'No (N)'	System	03 Nov 2020 02:48:23

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'f86d655e-cb8f-4a4d-8f74-b128ceaf2ec2'	System	03 Nov 2020 02:48:23
User entered '02 Nov 2020 20:48'	System	03 Nov 2020 02:48:23

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 5'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:35:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cf955e7d-6763-4052-be60-246b7d952e13'	System	04 Nov 2020 02:36:31
User entered 'Yes (Y)'	System	04 Nov 2020 02:36:31

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:17', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cf955e7d-6763-4052-be60-246b7d952e13'	System	04 Nov 2020 02:36:31
User entered '97.3'	System	04 Nov 2020 02:36:31

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cf955e7d-6763-4052-be60-246b7d952e13'	System	04 Nov 2020 02:36:31
User entered 'No (N)'	System	04 Nov 2020 02:36:31

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:25', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cf955e7d-6763-4052-be60-246b7d952e13'	System	04 Nov 2020 02:36:31
User entered '03 Nov 2020 20:36'	System	04 Nov 2020 02:36:31

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 6'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:46:55', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8c02d7bf-c9fb-4e62-aa68-6b51f6833daf'	System	05 Nov 2020 04:47:46
User entered 'Yes (Y)'	System	05 Nov 2020 04:47:46

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:36', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8c02d7bf-c9fb-4e62-aa68-6b51f6833daf'	System	05 Nov 2020 04:47:46
User entered '97.1'	System	05 Nov 2020 04:47:46

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8c02d7bf-c9fb-4e62-aa68-6b51f6833daf'	System	05 Nov 2020 04:47:46
User entered 'No (N)'	System	05 Nov 2020 04:47:46

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '8c02d7bf-c9fb-4e62-aa68-6b51f6833daf'	System	05 Nov 2020 04:47:46
User entered '04 Nov 2020 22:47'	System	05 Nov 2020 04:47:46

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 7'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '92c6f9c5-59de-4859-b223-711e0a6d83aa'	System	30 Oct 2020 15:21:06
User entered 'None (1)'	System	30 Oct 2020 15:21:06

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '92c6f9c5-59de-4859-b223-711e0a6d83aa'	System	30 Oct 2020 15:21:06
User entered 'No (N)'	System	30 Oct 2020 15:21:06

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '92c6f9c5-59de-4859-b223-711e0a6d83aa'	System	30 Oct 2020 15:21:06
User entered 'No (N)'	System	30 Oct 2020 15:21:06

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-30T10:20:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '92c6f9c5-59de-4859-b223-711e0a6d83aa'	System	30 Oct 2020 15:21:06
User entered 'None (1)'	System	30 Oct 2020 15:21:06

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:01', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '92c6f9c5-59de-4859-b223-711e0a6d83aa'	System	30 Oct 2020 15:21:06
User entered '30 Oct 2020 10:21'	System	30 Oct 2020 15:21:06

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 10:06'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:36'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-10-30T16:44:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b5639af1-bca5-4d16-9295-55acb4226633'	System	30 Oct 2020 21:45:31
User entered 'None (1)'	System	30 Oct 2020 21:45:31

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b5639af1-bca5-4d16-9295-55acb4226633'	System	30 Oct 2020 21:45:31
User entered 'No (N)'	System	30 Oct 2020 21:45:31

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b5639af1-bca5-4d16-9295-55acb4226633'	System	30 Oct 2020 21:45:31
User entered 'No (N)'	System	30 Oct 2020 21:45:31

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b5639af1-bca5-4d16-9295-55acb4226633'	System	30 Oct 2020 21:45:31
User entered 'None (1)'	System	30 Oct 2020 21:45:31

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:24', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'b5639af1-bca5-4d16-9295-55acb4226633'	System	30 Oct 2020 21:45:31
User entered '30 Oct 2020 16:45'	System	30 Oct 2020 21:45:31

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 13:31'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 2'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:45', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'bbb3c9c9-301e-439c-a8ad-7bb77edbb69a'	System	01 Nov 2020 05:31:15
User entered 'None (1)'	System	01 Nov 2020 05:31:15

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:54', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'bbb3c9c9-301e-439c-a8ad-7bb77edbb69a'	System	01 Nov 2020 05:31:15
User entered 'No (N)'	System	01 Nov 2020 05:31:15

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:30:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'bbb3c9c9-301e-439c-a8ad-7bb77edbb69a'	System	01 Nov 2020 05:31:15
User entered 'No (N)'	System	01 Nov 2020 05:31:15

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'bbb3c9c9-301e-439c-a8ad-7bb77edbb69a'	System	01 Nov 2020 05:31:15
User entered 'Does not interfere with activity (2)'	System	01 Nov 2020 05:31:15

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'bbb3c9c9-301e-439c-a8ad-7bb77edbb69a'	System	01 Nov 2020 05:31:15
User entered '01 Nov 2020 00:31'	System	01 Nov 2020 05:31:15

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 3'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be8cb98b-a525-4ba3-8f4c-5aa805f243f8'	System	02 Nov 2020 03:10:01
User entered 'None (1)'	System	02 Nov 2020 03:10:01

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be8cb98b-a525-4ba3-8f4c-5aa805f243f8'	System	02 Nov 2020 03:10:01
User entered 'No (N)'	System	02 Nov 2020 03:10:01

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:51', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be8cb98b-a525-4ba3-8f4c-5aa805f243f8'	System	02 Nov 2020 03:10:01
User entered 'No (N)'	System	02 Nov 2020 03:10:01

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:55', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be8cb98b-a525-4ba3-8f4c-5aa805f243f8'	System	02 Nov 2020 03:10:01
User entered 'Does not interfere with activity (2)'	System	02 Nov 2020 03:10:01

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:09:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'be8cb98b-a525-4ba3-8f4c-5aa805f243f8'	System	02 Nov 2020 03:10:01
User entered '01 Nov 2020 21:09'	System	02 Nov 2020 03:10:01

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 4'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3faaf2f8-68f8-42dc-8b2c-a08d0342b59d'	System	03 Nov 2020 02:48:44
User entered 'None (1)'	System	03 Nov 2020 02:48:44

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3faaf2f8-68f8-42dc-8b2c-a08d0342b59d'	System	03 Nov 2020 02:48:44
User entered 'No (N)'	System	03 Nov 2020 02:48:44

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:32', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3faaf2f8-68f8-42dc-8b2c-a08d0342b59d'	System	03 Nov 2020 02:48:44
User entered 'No (N)'	System	03 Nov 2020 02:48:44

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:37', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3faaf2f8-68f8-42dc-8b2c-a08d0342b59d'	System	03 Nov 2020 02:48:44
User entered 'Does not interfere with activity (2)'	System	03 Nov 2020 02:48:44

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '3faaf2f8-68f8-42dc-8b2c-a08d0342b59d'	System	03 Nov 2020 02:48:44
User entered '02 Nov 2020 20:48'	System	03 Nov 2020 02:48:44

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 5'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e7f4e82-796b-4081-aa0a-9cd27f458e14'	System	04 Nov 2020 02:37:00
User entered 'None (1)'	System	04 Nov 2020 02:37:00

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e7f4e82-796b-4081-aa0a-9cd27f458e14'	System	04 Nov 2020 02:37:00
User entered 'No (N)'	System	04 Nov 2020 02:37:00

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e7f4e82-796b-4081-aa0a-9cd27f458e14'	System	04 Nov 2020 02:37:00
User entered 'No (N)'	System	04 Nov 2020 02:37:00

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e7f4e82-796b-4081-aa0a-9cd27f458e14'	System	04 Nov 2020 02:37:00
User entered 'Does not interfere with activity (2)'	System	04 Nov 2020 02:37:00

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '5e7f4e82-796b-4081-aa0a-9cd27f458e14'	System	04 Nov 2020 02:37:00
User entered '03 Nov 2020 20:36'	System	04 Nov 2020 02:37:00

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 6'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:46', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '276f9600-b19b-41eb-9712-de780dca1a97'	System	05 Nov 2020 04:48:12
User entered 'None (1)'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '276f9600-b19b-41eb-9712-de780dca1a97'	System	05 Nov 2020 04:48:12
User entered 'No (N)'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:52', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '276f9600-b19b-41eb-9712-de780dca1a97'	System	05 Nov 2020 04:48:12
User entered 'No (N)'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-04T22:47:59', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '276f9600-b19b-41eb-9712-de780dca1a97'	System	05 Nov 2020 04:48:12
User entered 'Does not interfere with activity (2)'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:09', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '276f9600-b19b-41eb-9712-de780dca1a97'	System	05 Nov 2020 04:48:12
User entered '04 Nov 2020 22:48'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 7'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:05', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'None (0)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:08', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'None (0)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'None (0)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'None (0)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:24', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'None (0)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:29', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'None (0)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:38', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered 'No (N)'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T10:21:41', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'c4ca6a64-61f8-43a1-82e8-251041348378'	System	30 Oct 2020 15:21:45
User entered '30 Oct 2020 10:21'	System	30 Oct 2020 15:21:45

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 10:06'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:36'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:30', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'None (0)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'None (0)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:40', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'None (0)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:42', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'None (0)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:45', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'None (0)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:47', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'None (0)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered 'No (N)'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-10-30T16:45:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '021c8128-b6d4-4d2c-9459-20d2bc2a9edb'	System	30 Oct 2020 21:45:57
User entered '30 Oct 2020 16:45'	System	30 Oct 2020 21:45:57

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 13:31'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 2'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:16', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'None (0)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:22', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'None (0)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:25', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'None (0)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'None (0)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:32', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:35', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'None (0)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:39', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered 'No (N)'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T00:31:45', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'ef5a764d-f990-45ed-a75c-ebe3185b26cc'	System	01 Nov 2020 05:31:52
User entered '01 Nov 2020 00:31'	System	01 Nov 2020 05:31:52

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 3'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:02', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'None (0)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'None (0)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:07', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'None (0)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'None (0)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'None (0)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered 'No (N)'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-01T21:10:26', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '1aa21db2-654c-4434-a10b-9f7368ee706d'	System	02 Nov 2020 03:10:29
User entered '01 Nov 2020 21:10'	System	02 Nov 2020 03:10:29

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 4'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:44', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'None (0)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:48', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'None (0)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:50', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'None (0)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'None (0)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:55', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'None (0)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:48:58', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'None (0)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-02T20:49:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered 'No (N)'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-02T20:49:03', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'a7176612-1b44-4dc9-a12b-5c0946054fea'	System	03 Nov 2020 02:49:10
User entered '02 Nov 2020 20:49'	System	03 Nov 2020 02:49:10

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 5'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:36:57', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'None (0)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:00', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'None (0)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:04', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'None (0)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:08', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'None (0)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:10', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'None (0)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'None (0)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:19', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered 'No (N)'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-03T20:37:22', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: 'cfb48cd2-0917-4d22-9f23-03b750670e93'	System	04 Nov 2020 02:37:27
User entered '03 Nov 2020 20:37'	System	04 Nov 2020 02:37:27

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 6'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:13', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'None (0)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:15', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'None (0)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:18', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'None (0)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:20', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'None (0)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:23', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'None (0)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:25', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'None (0)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:28', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered 'No (N)'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-04T22:48:31', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '57e4dce2-ffb7-4e71-9fd9-2a26d06b5fee'	System	05 Nov 2020 04:48:36
User entered '04 Nov 2020 22:48'	System	05 Nov 2020 04:48:36

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Oct 2020 14:51:13
User entered 'Day 7'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:51:13

US3252602

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Nov 2020 04:48:12
User entered 'Day 8'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

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 (6985a5f7e2052c2f)', Time: '2020-11-06T17:35:36', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '2cbbba7ba-0598-42ce-a954-9672c7b268a9'	System	06 Nov 2020 23:35:49
User entered 'Yes (Y)'	System	06 Nov 2020 23:35:49

US3252602

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-06T17:35:43', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '2cbbba7ba-0598-42ce-a954-9672c7b268a9'	System	06 Nov 2020 23:35:49
User entered '06 Nov 2020 17:35'	System	06 Nov 2020 23:35:49

US3252602

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Nov 2020 04:48:12
User entered 'Day 8'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[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 (6985a5f7e2052c2f)', Time: '2020-11-06T17:35:49', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6fa96154-54af-4b9a-960b-85861288966a'	System	06 Nov 2020 23:36:02
User entered 'None (1)'	System	06 Nov 2020 23:36:02

US3252602

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6985a5f7e2052c2f)', Time: '2020-11-06T17:35:53', User OID: 'PatientReportedOutcome (US3252602)', ODM File OID: '6fa96154-54af-4b9a-960b-85861288966a'	System	06 Nov 2020 23:36:02
User entered '06 Nov 2020 17:35'	System	06 Nov 2020 23:36:02

US3252602

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 04:48:12

US3252602

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 26 Nov 2020 10:53:09

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 04:48:12

US3252602

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Nov 2020 03:58:25

US3252602

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	07 Nov 2020 03:58:25

US3252602

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	07 Nov 2020 03:58:25

US3252602

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Nov 2020 03:58:25

US3252602

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Nov 2020 03:58:30

US3252602

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Nov 2020 03:58:30

US3252602

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:36

US3252602

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:36

US3252602

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:36

US3252602

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'LEFT VOICE MAIL'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:36

US3252602

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:43

US3252602

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Nov 2020 03:56:43

US3252602

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:56

US3252602

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:56

US3252602

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:56

US3252602

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:53:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:56:56

US3252602

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	21 Nov 2020 03:57:01

US3252602

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:53:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Nov 2020 03:57:01

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 11:34:09

US3252602

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:53:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:34:09
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 11:34:09

US3252602

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:53:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	06 Nov 2020 22:50:49
User entered 'No (N)'	Shannon Moyer (b) (4)	03 Oct 2020 04:22:49

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:03:47
User entered 'USA-US108-2020-mRNA-1273-P301000016'	System	09 Nov 2020 14:03:42
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 14:03:42

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:56:52
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:53:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:53:27
Data point term sent to Coder	System	06 Nov 2020 22:53:12
User entered 'Appendicitis'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:56:58
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:02
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:04
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:09
User entered '6 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:48:08
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	24 Nov 2020 19:10:24
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 19:10:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 19:00:08
User entered '10:00' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Nov 2020 19:00:08
User entered empty.	Joanna Gurrola (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:10:24
User entered '6 Nov 2020 10:00'	System	24 Nov 2020 19:00:08
User entered empty.	System	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:54
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:56
User entered '6 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:57:59
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:01
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:05
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:18
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:19
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Nov 2020 19:07:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		24 Nov 2020 19:07:06
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Nov 2020 22:52:41
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:40
User entered '6 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'It's provided. ' (Site from Safety).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 19:09:38
User entered '6 Nov 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	23 Nov 2020 08:38:57
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:18:26
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 19:07:06
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 19:07:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Nov 2020 00:58:47
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Participant was not hospitalized or System Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).		24 Nov 2020 19:07:26
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	24 Nov 2020 19:07:26
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 19:07:26
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	24 Nov 2020 19:07:06
DataPoint Un-verified.	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 19:07:06
User entered '0' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 19:07:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	21 Nov 2020 00:58:49
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:58:51
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:03:59
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:04:02
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:37:22
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:04:09
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:37:23
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:45:10
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'updated' (Site from Safety).	Shannon Moyer (b) (4)	23 Nov 2020 08:40:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 08:40:39
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:18:47
User entered 'None (NONE)'	Joanna Gurrola (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[None](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:05:12
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:19:09
User opened query 'PV Query: Please provide pathology report when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:19:01
User opened query 'PV Query: Please provide the surgical report when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:18:53
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:18:37
User entered 'PATIENT GOT APPENDICITIS TODAY AND GOT AN APPENDECTOMY.' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	06 Nov 2020 22:53:08
User entered 'Patient got appendicitis today and got an appendectomy. q'	Joanna Gurrola (b) (4)	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 22:52:41

US3252602

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:53:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 19:07:06

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:53:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:15:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[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-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:22:42
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 Oct 2020 05:22:42
Data point term sent to Coder	System	03 Oct 2020 04:16:45
User entered 'Naproxen'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Indication](#)

Audit	User	Time (GMT)
User entered 'Lumbar Radiculopathy'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '375'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH#2 (SEP 2010). Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:24:31
User entered 'UN Jan 2018'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 04:16:30

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:14:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:14:41
Data point term sent to Coder	System	03 Oct 2020 04:18:45
User entered 'Cyclobenzaprine'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Indication](#)

Audit	User	Time (GMT)
User entered 'Lumbar Radiculopathy'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH#2 (SEP 2010). Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:26:03
User entered '28 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 04:17:50

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:08:46
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 Oct 2020 07:08:46
Data point term sent to Coder	System	03 Oct 2020 04:20:46
User entered 'Gabapentin'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Indication](#)

Audit	User	Time (GMT)
User entered 'Lumbar Radiculopathy'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH#2 (SEP 2010). Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:26:46
User entered '23 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Oct 2020 04:19:47

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:23:53
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 Oct 2020 04:23:53
Data point term sent to Coder	System	03 Oct 2020 04:22:47
User entered 'alendronate sodium'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Indication](#)

Audit	User	Time (GMT)
User entered 'Osteopenia'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '35'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every week (QS)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:53:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	03 Oct 2020 04:22:04

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:53:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	06 Nov 2020 22:53:19
User entered 'No (N)'	Shannon Moyer (b) (4)	03 Oct 2020 04:22:32

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:53:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:07:44
User entered '6 Nov 2020'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:53:37

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:53:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:07:45
User entered 'Appendectomy'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:53:37

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:53:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:07:47
User entered 'Adverse Event (AE)'	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:53:37

US3252602

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:53:09

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 01:07:49
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	06 Nov 2020 22:53:37

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'USA-US108-2020-MRNA-1273-P301000016'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Yes (Y)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Yes (Y)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Joel'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Solis'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered '5201 N. 10th Street'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Mcallen'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'TX'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'carmpa'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:45:22
User entered 'US'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 14:45:35
User entered '1'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'USA-US108-2020-MRNA-1273-P301000016'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Yes (Y)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Yes (Y)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Joel'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Solis'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered '5201 N. 10th Street'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Mcallen'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'TX'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'carmpa'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:45:22
User entered 'US'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 14:45:35
User entered '1'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:53:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 14:39'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:53:09

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)	24 Nov 2020 14:45:22
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'USA-US108-2020-MRNA-1273-P301000016'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Yes (Y)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Yes (Y)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'No (N)'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Joel'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Solis'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered '5201 N. 10th Street'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'Mcallen'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'TX'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:39:17
User entered 'carmpa'	System	09 Nov 2020 14:03:42

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:45:22
User entered 'US'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 26 Nov 2020 10:53:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 14:45:35
User entered '1'	System	09 Nov 2020 14:39:24

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:53:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 14:45'	System	24 Nov 2020 14:45:35

US3252602

Folder: SAE USA-US108-2020-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:53:09

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 'I'	(b) (4), (b) (6)	24 Nov 2020 14:45:35