

US3322329 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:02

All time stamps listed in this document are displayed in GMT

US3322329

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:02

[Participant ID](#)

US3322329

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

US3322329

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 SEP 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

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" 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

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3322329

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:02

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3322329

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:02

Were any significant conditions reported?

Yes ☒

No ☐

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2007
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 UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

Condition	FOOT SURGERY
Start date (dd MMM yyyy)	UN UNK 2018
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 UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

Condition	CERVICAL DYSPLASIA
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

Condition	TENNIS INJURY-LEFT FOOT
Start date (dd MMM yyyy)	UN UNK 2018
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 UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:15
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	215.8 lb
BMI (<i>xxx.x</i>)	28.53091 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322329

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

Date of assessment (<i>dd MMM yyyy</i>)	12 SEP 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 UNK 2007
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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	

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 SEP 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

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

What was the date of randomization? (dd MMM yyyy) 12 SEP 2020

What was the participant's randomization number? 113720

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 ☒

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Height	ND - Not Done
Weight	ND - Not Done

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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)	12 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:30
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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)	12 SEP 2020
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:37
Temperature (xxx.x)	94.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3322329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

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.

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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)	12 SEP 2020
What was the treatment time? (00:00-23:59)	12:07 (24 HR)
Treatment Date and Time (derived)	12 SEP 2020 12:07
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

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:40 (24 HR)
Collection date and time (derived)	12 SEP 2020 11:40

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:02

Collection date (<i>dd MMM yyyy</i>)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	12 SEP 2020 11:35
Nasopharyngeal Swab 2	No		

US3322329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

94.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:48

PC Open Date & Time

12 SEP 2020 12:27

PC Close Date & Time

12 SEP 2020 14:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	12 SEP 2020 17:31
PC Open Date & Time	12 SEP 2020 15:52
PC Close Date & Time	13 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

97.3 °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

13 SEP 2020 16:52

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

14 SEP 2020 14:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

15 SEP 2020 15:24

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	16 SEP 2020 21:18
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

97.3 °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

18 SEP 2020 09:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 07:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

12 SEP 2020 12:50

PC Open Date & Time

12 SEP 2020 12:27

PC Close Date & Time

12 SEP 2020 14:57

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

12 SEP 2020 17:32

PC Open Date & Time

12 SEP 2020 15:52

PC Close Date & Time

13 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 16:57

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

25

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 14:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

15 SEP 2020 15:40

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

16 SEP 2020 21:18

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 09:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 07:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 12:50
PC Open Date & Time	12 SEP 2020 12:27
PC Close Date & Time	12 SEP 2020 14:57

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 17:33
PC Open Date & Time	12 SEP 2020 15:52
PC Close Date & Time	13 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:58
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 14:58
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 15:40
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 21:26
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 09:45
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 07:29
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:01:02

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 19 SEP 2020 12:35

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 9

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 20 SEP 2020 12:30

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

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	19 SEP 2020 12:35
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

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	20 SEP 2020 12:30
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted?

Yes ☒

No ☐

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

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted?

Yes ☒

No ☐

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

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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)	15 OCT 2020
Time of assessment (00:00-23:59)	08:50 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:50
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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)	15 OCT 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:26
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3322329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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)	15 OCT 2020
What was the treatment time? (00:00-23:59)	09:56 (24 HR)
Treatment Date and Time (derived)	15 OCT 2020 09:56
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

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:25 (24 HR)
Collection date and time (derived)	15 OCT 2020 09:25

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:02

Collection date (<i>dd MMM yyyy</i>)			15 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	09:20	15 OCT 2020 09:20
Nasopharyngeal Swab 2	No		

US3322329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

15 OCT 2020 10:25

PC Open Date & Time

15 OCT 2020 10:16

PC Close Date & Time

15 OCT 2020 12:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °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):

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

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

PC Time Stamp 16 OCT 2020 02:01

PC Open Date & Time 15 OCT 2020 13:41

PC Close Date & Time 16 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 OCT 2020 13:28

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

97.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 OCT 2020 12:03

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 16:19

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

19 OCT 2020 22:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 23:32

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 22:20

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

15 OCT 2020 10:26

PC Open Date & Time

15 OCT 2020 10:16

PC Close Date & Time

15 OCT 2020 12:46

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

20

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 02:02

PC Open Date & Time

15 OCT 2020 13:41

PC Close Date & Time

16 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

76

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 13:22

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 ☐

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

100

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)**

125

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 12:01

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 ☐

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

64

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)**

55

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 16:20

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 ☐

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

50

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)**

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 22:54

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 ☐

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

40

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

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

Yes ☒

No ☐

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

25

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 23:33

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	35
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm)	20
Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	21 OCT 2020 22:21
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 10:26
PC Open Date & Time	15 OCT 2020 10:16
PC Close Date & Time	15 OCT 2020 12:46

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 02:03
PC Open Date & Time	15 OCT 2020 13:41
PC Close Date & Time	16 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 13:23
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

		Yes <input type="checkbox"/>
PC Time stamp	17 OCT 2020 12:02	
PC Open Date & Time	17 OCT 2020 12:00	
PC Close Date & Time	18 OCT 2020 11:59	

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 16:21
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 22:55
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 23:45
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 ☒

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 22:22
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT	DAY 8
Is there any REDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time Stamp	22 OCT 2020 13:21
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 8

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

Yes ☒

No ☐

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

25

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

PC Time stamp

22 OCT 2020 13:22

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 9

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

Yes ☐

No ☒

PC Time stamp

23 OCT 2020 14:21

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

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	22 OCT 2020 13:22
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

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	23 OCT 2020 14:21
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted?

Yes ☒

No ☐

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

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted?

Yes ☒

No ☐

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

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted?

Yes ☒

No ☐

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

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 09:30
Temperature (<i>xxx.x</i>)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 NOV 2020

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

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	17 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:24 (24 HR)
Collection date and time (derived)	17 NOV 2020 10:24

US3322329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 09:07:27

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 14:42:48

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

09 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 06:45:49

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2021 00:01
Patient Cloud Close Date & Time	14 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	25 JUN 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 376

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	08 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	20 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	14 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	21 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	28 JAN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	25 FEB 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
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Patient Cloud Close Date & Time	08 APR 2022 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	01 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	22 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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 <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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	11 NOV 2022 23:59

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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="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"/>

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	18 NOV 2022 23:59

US3322329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322329

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322329

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:02

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"/>

US3322329

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:01:02

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3322329

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:02

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

AEID	USA-US060-2020-MRNA-1273-P30 1000006
Adverse event	FACIAL SWELLING
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)	17 OCT 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)	22 OCT 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	343 of 1785

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" 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	True
Concomitant Procedure	False
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	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

SAE TERM: FACIAL SWELLING;
INTENSITY: SEVERE;
CAUSALITY: CONSIDERED IP
RELATED GIVEN IT OCCURRED
ON DAY 3 OF OBSERVATION
PERIOD POST-VACCINATION.
THE PRIOR COSMETIC
PROCEDURE BELIEVED TO
HAVE BEEN A CONTRIBUTING
FACTOR BUT NOT THE CAUSE
SINCE THE PROCEDURE WAS
ALMOST 2 WEEKS BEFORE THE
FACIAL SWELLING. A SAFETY
CALL WAS MADE ON 20 OCT
2020 DUE TO PATIENT
REPORTING GRADE 3
INJECTION SITE SWELLING.
SUBJECT CONFIRMED
EXPERIENCING INJECTION SITE
SWELLING/HARDNESS
MEASURING 125MM ON DAY 3
WHICH CAME DOWN TO 55MM
BY DAY 4. SHE EXPERIENCED
MILD DELTOID TENDERNESS
BUT DID NOT HAVE ANY
TROUBLE MOVING THE
AFFECTED ARM. DURING THIS
SAFETY CALL, THE SUBJECT
REPORTED RECEIVING
MEDICAL ATTENTION ON 17
OCTOBER 2020 DUE TO FACIAL
SWELLING. PATIENT STATED
SHE GOT DERMAL FILLER
(VOLUMA -CROSSLINKED
HYALURONIC ACID) COSMETIC
INJECTIONS IN CHEEKS ON 02
OCT 2020 PRIOR TO RECEIVING

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

SECOND IP. IT WAS A PLANNED
PROCEDURE, AND SHE FORGOT
TO MENTION IT WHEN SHE
CAME ONSITE FOR HER
SECOND VACCINE ON 15 OCT
2020. DURING HER VISIT 2, THE
PHYSICAL EXAM WAS
NORMAL INCLUDING SKIN.
PATIENT STATED SHE
DEVELOPED BILATERAL
FACIAL SWELLING (LEFT
GREATER THAN RIGHT) THE
NIGHT OF 17 OCT 2020. SHE
CONTACTED THE DOCTOR
THAT DID THE COSMETIC
PROCEDURE, AND SHE WAS
PRESCRIBED PREDNISOLONE
FOR 5 DAYS. SHE TOOK
PREDNISOLONE 25MG ON 17
OCT 2020 AT 10 AM AND
PREDNISOLONE 40MG DAILY
THEREAFTER. ON 20 OCT 2020,
THE FACIAL SWELLING WAS
ALMOST COMPLETELY
RESOLVED WITH ONLY
MINIMAL SWELLING UNDER
THE LEFT EYE. THE REASON
SHE CALLED HER DOCTOR AND
THE REASON FOR TREATMENT
WITH PREDNISOLONE WAS THE
FACIAL SWELLING NOT IP
INJECTION SITE SWELLING.
FACIAL SWELLING IS A
POTENTIAL SIDE-EFFECT OF
VOLUMA DERMAL FILLER
TOPICAL INJECTIONS, AND I
BELIEVE THE INJECTION OF

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

DERMAL FILLER WAS A
CONTRIBUTING FACTOR TO
THE PATIENT DEVELOPING
FACIAL SWELLING.

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)	
--	--

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:02

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

Yes ☒

No ☐

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

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

Name of Medication	NAPROXEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MUSCLE PAIN
Dose per administration	500
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 type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" 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"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

	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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

Name of Medication	ESTRADIOL PELLET
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST MENOPAUSAL
Dose per administration	25
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 type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	EVERY 3 MONTHS Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

	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	UNK 2014
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"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

Name of Medication	TESTOSTERONE PELLET
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST MENOPAUSAL
Dose per administration	87.5
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 type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

	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)	UN	UNK 2014
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

Name of Medication	PREDNISOLONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FACIAL SWELLING
Dose per administration	25
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"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

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)	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 17 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="radio"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

Name of Medication	PREDNISOLONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	FACIAL SWELLING
Dose per administration	40
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"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

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)	18 OCT 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"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

Name of Medication	VOLUMA (CROSSLINKED HYALURONIC ACID)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COSMETIC PROCEDURE
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" 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 checked="" 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 type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input checked="" type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
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"/>

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:02

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:01:02

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	DERMAL FILLER INJECTION	Other	COSMETIC

US3322329

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:01:02

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

US3322329

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:01:02

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 ☐

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

SAEID	USA-US060-2020-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:02

SAEID	USA-US060-2020-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/OCT/2020 18:43
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:02

SAEID	USA-US060-2020-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 22:15
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:01:02

SAEID	USA-US060-2020-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 15:39
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.	<input checked="" type="checkbox"/> True

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:01:02

SAEID	USA-US060-2020-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/NOV/2020 10:40
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

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:01:02

SAEID	USA-US060-2020-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3322329 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322329

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:02

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3322329'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Sep 2020 15:14:27

US3322329

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:55:57

US3322329

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Sep 2020 15:14:28

US3322329

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:55:57

US3322329

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	12 Sep 2020 17:55:57

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1968'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Sep 2020 15:14:29

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Age](#)

Audit	User	Time (GMT)
User entered '51'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

White

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

Unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:02

Not reported

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:56:31

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:22

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Sep 2020 15:14:28

US3322329

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:02

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:36

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
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)	12 Sep 2020 17:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Sep 2020 17:59:44
Data point term sent to Coder	System	12 Sep 2020 17:58:56
User entered 'Hysterectomy'	Elisa Moralez (b) (4)	12 Sep 2020 17:58:54
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Elisa Morales (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 17:58:54
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 17:58:54
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2007'	System	12 Sep 2020 17:58:54

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:56:55
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated, please see line 4' (Site from DM).	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:52:01
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:55:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Foot operation, LLT: Foot surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 18:00:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 18:00:45
Data point term sent to Coder	System	12 Sep 2020 17:59:58
User entered 'Foot surgery'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Elisa Morales (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4)	12 Sep 2020 17:59:09
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2018'	System	12 Sep 2020 17:59:09

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Cervical dysplasia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 20:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Oct 2020 20:12:21
Data point term sent to Coder	System	14 Oct 2020 20:11:39
User entered 'Cervical dysplasia'	Frances Saubon (b) (4)	14 Oct 2020 20:11:28
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Frances Saubon (b) (4)	14 Oct 2020 20:11:28
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4)	14 Oct 2020 20:11:28
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Frances Saubon (b) (4)	14 Oct 2020 20:11:28
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2007'	Frances Saubon (b) (4) (b) (4)	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4)	14 Oct 2020 20:11:28
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 20:11:28

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Sports injury, LLT: Sports injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:01:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:01:28
Data point term sent to Coder	System	20 Oct 2020 21:52:42
User entered 'Tennis injury-left Foot'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Frances Saubon (b) (4)	20 Oct 2020 21:51:49
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'No (N)'	Frances Saubon (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'UN UNK 2018'	Frances Saubon (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Frances Saubon (b) (4)	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Oct 2020 21:51:49

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 00:26:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 00:26:00
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
Data point term sent to Coder	System	02 Nov 2020 16:45:34
User entered 'post menopausal'	Elisa Moralez (b) (4)	02 Nov 2020 16:44:46
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'un UNK 2014'	Elisa Morales (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:07:28
User entered '0'	Elisa Moralez (b) (4)	02 Nov 2020 16:44:46
	(b) (4)	

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '2014'	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 16:44:46

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
Query 'Per CDM: Please confirm if time 10:15 is AM or PM. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 13:51:10
User opened query 'Per CDM: Please confirm if time 10:15 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:32:03
User entered '10:15'	Elisa Moralez (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 10:15'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '73' in	Elisa Moralez (b) (4)	12 Sep 2020 17:59:36
DataPoint set to visible.	(b) (4) System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '215.8' lb	Elisa Moralez (b) (4)	12 Sep 2020 17:59:36
DataPoint set to visible.	(b) (4) System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '28.53091'	System	12 Sep 2020 17:59:36
DataPoint set to visible.	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	12 Sep 2020 17:59:36
DataPoint set to visible.	System	12 Sep 2020 17:03:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Sep 2020 17:59:36

US3322329

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:44

US3322329

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:44

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:47:14
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'please see updated medical history' (Site from DM).	Frances Saubon (b) (4)	14 Oct 2020 20:11:52
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:29:34
User entered 'Surgically sterile (SURGICALLY STERILE)'	Elisa Moralez (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'UN UNK 2007'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:01:02

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 17:59:57

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:02

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:21

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	12 Sep 2020 18:00:42

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Sep 2020 16:24:19

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '113720'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Sep 2020 16:24:19

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

[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) [REDACTED]	12 Sep 2020 16:24:19

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

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)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:01:36

US3322329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4)	23 Sep 2020 19:30:21
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 09:05:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:05:38

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '10:30'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 10:30'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Pulse (xxx)

Audit	User	Time (GMT)
User entered '62'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '14'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:02

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12:37'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:37'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 06:55:26
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	(b) (4), (b) (6)	17 Sep 2020 20:04:33
answered with 'NCS' (Site from System).		
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:34:05
User entered '94.8' F	Elisa Moralez (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Pulse (xxx)

Audit	User	Time (GMT)
User entered '60'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '14'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Sep 2020 18:02:43

US3322329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:47

US3322329

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:47

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12:07'	Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:07'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 17:10:21

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:40'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:40'	System	12 Sep 2020 18:02:57

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:35'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:35'	System	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	System	12 Sep 2020 18:03:05

US3322329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Sep 2020 18:03:08

US3322329

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Sep 2020 18:03:08

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:47:22', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f'	System	12 Sep 2020 17:48:50
User entered 'Yes (Y)'	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:48:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f'	System	12 Sep 2020 17:48:50
User entered '94.8'	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:48:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f'	System	12 Sep 2020 17:48:50
User entered 'No (N)'	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:48:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '777c4804-9c50-410d-b8c7-df5185ebf16f'	System	12 Sep 2020 17:48:50
User entered '12 Sep 2020 12:48'	System	12 Sep 2020 17:48:50

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 14:57'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:30:06', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663'	System	12 Sep 2020 22:31:57
User entered 'Yes (Y)'	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663'	System	12 Sep 2020 22:31:57
User entered '98.0'	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663'	System	12 Sep 2020 22:31:57
User entered 'No (N)'	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '48d9f6be-e7ec-4ee8-919d-28c8001e2663'	System	12 Sep 2020 22:31:57
User entered '12 Sep 2020 17:31'	System	12 Sep 2020 22:31:57

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 2'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1'	System	13 Sep 2020 21:52:46
User entered 'Yes (Y)'	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1'	System	13 Sep 2020 21:52:46
User entered '97.3'	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1'	System	13 Sep 2020 21:52:46
User entered 'No (N)'	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:52:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '2f7c54b2-c80c-47f8-a7fd-0d92e59655d1'	System	13 Sep 2020 21:52:46
User entered '13 Sep 2020 16:52'	System	13 Sep 2020 21:52:46

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 3'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:56:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6'	System	14 Sep 2020 19:57:09
User entered 'Yes (Y)'	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:56:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6'	System	14 Sep 2020 19:57:09
User entered '97.5'	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6'	System	14 Sep 2020 19:57:09
User entered 'No (N)'	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '410f6419-0a2a-4aae-b0f6-2c142a6c5dd6'	System	14 Sep 2020 19:57:09
User entered '14 Sep 2020 14:57'	System	14 Sep 2020 19:57:09

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 4'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64'	System	15 Sep 2020 20:24:49
User entered 'Yes (Y)'	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64'	System	15 Sep 2020 20:24:49
User entered '97.5'	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64'	System	15 Sep 2020 20:24:49
User entered 'No (N)'	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:24:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6e51b65-716b-44f3-a61e-64d3af349b64'	System	15 Sep 2020 20:24:49
User entered '15 Sep 2020 15:24'	System	15 Sep 2020 20:24:49

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 5'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1'	System	17 Sep 2020 02:18:07
User entered 'Yes (Y)'	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:41', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1'	System	17 Sep 2020 02:18:07
User entered '98.0'	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1'	System	17 Sep 2020 02:18:07
User entered 'Yes (Y)'	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant took medication to treat muscle pain after exercise. ' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 08:44:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Sep 2020 02:18:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1'	System	17 Sep 2020 02:18:07
User entered '1'	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:17:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1' User entered '0'	System	17 Sep 2020 02:18:07
	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ee541394-747f-4ad9-b488-7f1ca6d86ca1'	System	17 Sep 2020 02:18:07
User entered '16 Sep 2020 21:18'	System	17 Sep 2020 02:18:07

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 6'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a'	System	18 Sep 2020 14:44:36
User entered 'Yes (Y)'	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a' User entered '97.3'	System	18 Sep 2020 14:44:36
	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a'	System	18 Sep 2020 14:44:36
User entered 'No (N)'	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5de159f6-e24b-42a6-95a4-68ed3c706e8a' User entered '18 Sep 2020 09:44'	System	18 Sep 2020 14:44:36
	System	18 Sep 2020 14:44:36

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 7'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b'	System	19 Sep 2020 12:28:20
User entered 'Yes (Y)'	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b'	System	19 Sep 2020 12:28:20
User entered '97.6'	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b'	System	19 Sep 2020 12:28:20
User entered 'No (N)'	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '8115fcba-c748-4921-a4e1-fb38b065799b' User entered '19 Sep 2020 07:28'	System	19 Sep 2020 12:28:20
	System	19 Sep 2020 12:28:20

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:49:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a'	System	12 Sep 2020 17:50:12
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:49:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a'	System	12 Sep 2020 17:50:12
User entered 'No (N)'	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a'	System	12 Sep 2020 17:50:12
User entered 'No (N)'	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a' User entered 'None (1)'	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '03943e6f-2b15-4284-aaed-40680ab32f6a'	System	12 Sep 2020 17:50:12
User entered '12 Sep 2020 12:50'	System	12 Sep 2020 17:50:12

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 14:57'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:31:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace'	System	12 Sep 2020 22:32:28
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace'	System	12 Sep 2020 22:32:28
User entered 'No (N)'	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace'	System	12 Sep 2020 22:32:28
User entered 'No (N)'	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace'	System	12 Sep 2020 22:32:28
User entered 'None (1)'	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'de660c33-4a56-4409-8c75-53b700492ace'	System	12 Sep 2020 22:32:28
User entered '12 Sep 2020 17:32'	System	12 Sep 2020 22:32:28

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 2'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:54:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a'	System	13 Sep 2020 21:57:16
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:54:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a'	System	13 Sep 2020 21:57:16
User entered 'No (N)'	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:54:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a'	System	13 Sep 2020 21:57:16
User entered 'Yes (Y)'	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered '20'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:56:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered 'None (1)'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b9bf29a-1d41-4e8e-bf63-159b7beb461a' User entered '13 Sep 2020 16:57'	System	13 Sep 2020 21:57:16
	System	13 Sep 2020 21:57:16

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 3'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c'	System	14 Sep 2020 19:57:54
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c'	System	14 Sep 2020 19:57:54
User entered 'No (N)'	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c'	System	14 Sep 2020 19:57:54
User entered 'Yes (Y)'	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered '25'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c' User entered 'None (1)'	System	14 Sep 2020 19:57:54
	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e4a53382-dd0c-432f-b066-63d52055707c'	System	14 Sep 2020 19:57:54
User entered '14 Sep 2020 14:57'	System	14 Sep 2020 19:57:54

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 4'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'No (N)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'No (N)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered 'None (1)'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '947df295-442e-40b8-bef0-3a9869ef2464'	System	15 Sep 2020 20:40:27
User entered '15 Sep 2020 15:40'	System	15 Sep 2020 20:40:27

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 5'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987'	System	17 Sep 2020 02:18:41
User entered 'None (1)'	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987'	System	17 Sep 2020 02:18:41
User entered 'No (N)'	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987'	System	17 Sep 2020 02:18:41
User entered 'No (N)'	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987'	System	17 Sep 2020 02:18:41
User entered 'None (1)'	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:18:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '79586f86-0d92-4725-9c80-7d9715fb1987'	System	17 Sep 2020 02:18:41
User entered '16 Sep 2020 21:18'	System	17 Sep 2020 02:18:41

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 6'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:39', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa'	System	18 Sep 2020 14:44:58
User entered 'None (1)'	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa'	System	18 Sep 2020 14:44:58
User entered 'No (N)'	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa'	System	18 Sep 2020 14:44:58
User entered 'No (N)'	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered 'None (1)'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:44:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7aa9ec87-7613-48b1-9554-c0820edbf2fa' User entered '18 Sep 2020 09:44'	System	18 Sep 2020 14:44:58
	System	18 Sep 2020 14:44:58

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 7'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0'	System	19 Sep 2020 12:28:45
User entered 'None (1)'	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0'	System	19 Sep 2020 12:28:45
User entered 'No (N)'	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0'	System	19 Sep 2020 12:28:45
User entered 'No (N)'	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0'	System	19 Sep 2020 12:28:45
User entered 'None (1)'	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'a28ad5cd-58a6-460a-bcf9-6c134fd06fc0'	System	19 Sep 2020 12:28:45
User entered '19 Sep 2020 07:28'	System	19 Sep 2020 12:28:45

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'None (0)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'None (0)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'None (0)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'None (0)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'None (0)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'None (0)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered 'No (N)'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T12:50:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b1d5d57f-eabf-4b10-bd3b-f3f4928b7489'	System	12 Sep 2020 17:50:39
User entered '12 Sep 2020 12:50'	System	12 Sep 2020 17:50:39

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:27'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 14:57'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'None (0)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'None (0)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'None (0)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'None (0)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:32:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'None (0)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:33:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d'	System	12 Sep 2020 22:33:12
User entered 'No (N)'	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-12T17:33:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bc73e8d5-99c1-4709-91f3-cdc711db287d' User entered '12 Sep 2020 17:33'	System	12 Sep 2020 22:33:12
	System	12 Sep 2020 22:33:12

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 15:52'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 2'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'None (0)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'Some interference with activity (2)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'None (0)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'None (0)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'None (0)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'None (0)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:57:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad'	System	13 Sep 2020 21:58:02
User entered 'No (N)'	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-13T16:58:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f3131cc3-9f6e-48ee-821e-b0a5ba079bad' User entered '13 Sep 2020 16:58'	System	13 Sep 2020 21:58:02
	System	13 Sep 2020 21:58:02

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 3'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:57:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'No interference with activity (1)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'None (0)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'None (0)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'None (0)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'None (0)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:11', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'None (0)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered 'No (N)'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-14T14:58:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7dcc9dbc-34a2-47dd-bc13-425d1337ed8e'	System	14 Sep 2020 19:58:22
User entered '14 Sep 2020 14:58'	System	14 Sep 2020 19:58:22

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 4'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'None (0)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'No interference with activity (1)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:39', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'None (0)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'None (0)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'None (0)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'None (0)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered 'No (N)'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-15T15:40:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '5998d42c-c86d-4e5b-bea9-c9862549e3e2'	System	15 Sep 2020 20:40:58
User entered '15 Sep 2020 15:40'	System	15 Sep 2020 20:40:58

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 5'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'None (0)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:06', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'None (0)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'No interference with activity (1)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'None (0)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'None (0)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:22', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'None (0)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered 'No (N)'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-16T21:26:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '74442301-b4be-4ab4-a60f-c33d06015118'	System	17 Sep 2020 02:26:33
User entered '16 Sep 2020 21:26'	System	17 Sep 2020 02:26:33

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 6'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'None (0)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'None (0)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:03', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'None (0)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'None (0)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'None (0)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'None (0)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered 'No (N)'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-18T09:45:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '16fa8c02-e8d2-4f37-b8f6-c36671abdc3b'	System	18 Sep 2020 14:45:18
User entered '18 Sep 2020 09:45'	System	18 Sep 2020 14:45:18

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 7'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'None (0)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:28:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'None (0)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'No interference with activity (1)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'None (0)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:10', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'None (0)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'None (0)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411'	System	19 Sep 2020 12:29:34
User entered 'No (N)'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T07:29:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '36ca5ece-c1b0-4f7a-aed2-5a23a9220411' User entered '19 Sep 2020 07:29'	System	19 Sep 2020 12:29:34
	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 8'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9edabda2-4c9f-49ca-868a-bfcd008ea00'	System	19 Sep 2020 17:35:37
User entered 'No interference with activity (1)'	System	19 Sep 2020 17:35:37

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9edabda2-4c9f-49ca-868a-bfcd008ea00'	System	19 Sep 2020 17:35:37
User entered '19 Sep 2020 12:35'	System	19 Sep 2020 17:35:37

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 9'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a0bb73c-89a9-4624-b8b3-e265c9e75844'	System	20 Sep 2020 17:30:45
User entered 'None (0)'	System	20 Sep 2020 17:30:45

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a0bb73c-89a9-4624-b8b3-e265c9e75844'	System	20 Sep 2020 17:30:45
User entered '20 Sep 2020 12:30'	System	20 Sep 2020 17:30:45

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 8'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:39', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b757d689-159b-4d13-959c-f1fff87c7411'	System	19 Sep 2020 17:35:47
User entered 'No (N)'	System	19 Sep 2020 17:35:47

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-19T12:35:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b757d689-159b-4d13-959c-f1fff87c7411'	System	19 Sep 2020 17:35:47
User entered '19 Sep 2020 12:35'	System	19 Sep 2020 17:35:47

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 12:29:34
User entered 'Day 9'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '94162ac8-5060-43dc-9b43-71558aeb82b3'	System	20 Sep 2020 17:30:56
User entered 'No (N)'	System	20 Sep 2020 17:30:56

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-09-20T12:30:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '94162ac8-5060-43dc-9b43-71558aeb82b3'	System	20 Sep 2020 17:30:56
User entered '20 Sep 2020 12:30'	System	20 Sep 2020 17:30:56

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 12:29:34

US3322329

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 12:29:34

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:15

US3322329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 19:29:19

US3322329

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 19:29:19

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:24

US3322329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 17:50:37

US3322329

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 17:50:37

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:16

US3322329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:47:24

US3322329

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 19:47:24

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	15 Oct 2020 16:46:06

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '08:50'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 08:50'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '13'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '10:26'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 10:26'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.0' F	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Pulse (xxx)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '135'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '85'	(b) (4), (b) (6)	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:46:59

US3322329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:47:34

US3322329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:47:34

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '09:56'	Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 09:56'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 14:57:38

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:25'	(b) (4), (b) (6)	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 09:25'	System	15 Oct 2020 16:48:01

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:20'	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '15 Oct 2020 09:20'	System	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:48:19

US3322329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 16:48:26

US3322329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 16:48:26

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381'	System	15 Oct 2020 15:25:40
User entered 'Yes (Y)'	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381'	System	15 Oct 2020 15:25:40
User entered '97.0'	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381'	System	15 Oct 2020 15:25:40
User entered 'No (N)'	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '34504d6f-6378-416a-9b77-5bc333003381' User entered '15 Oct 2020 10:25'	System	15 Oct 2020 15:25:40
	System	15 Oct 2020 15:25:40

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 10:16'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:46'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	System	16 Oct 2020 07:01:08
User entered 'Yes (Y)'	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	System	16 Oct 2020 07:01:08
User entered '98.9'	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	System	16 Oct 2020 07:01:08
User entered 'Yes (Y)'	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 05:50:12
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with, please see conmeds' (Site from System).	Frances Saubon (b) (4)	22 Oct 2020 14:51:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 07:01:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	System	16 Oct 2020 07:01:08
User entered '1'	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:00:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608'	System	16 Oct 2020 07:01:08
User entered '0'	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '67959f20-7524-42e9-822b-b901ab9c7608' User entered '16 Oct 2020 02:01'	System	16 Oct 2020 07:01:08
	System	16 Oct 2020 07:01:08

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 13:41'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 2'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:27:51', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb'	System	16 Oct 2020 18:29:02
User entered 'Yes (Y)'	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:27:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '98.2'	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:41', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb'	System	16 Oct 2020 18:29:02
User entered 'Yes (Y)'	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 05:50:15
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with, please see conmeds' (Site from System).	Frances Saubon (b) (4)	22 Oct 2020 14:51:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Oct 2020 18:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb'	System	16 Oct 2020 18:29:02
User entered '1'	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '0'	System	16 Oct 2020 18:29:02
	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:28:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b6342c43-5174-4630-8b66-bba4a416e0eb' User entered '16 Oct 2020 13:28'	System	16 Oct 2020 18:29:02

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 3'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248'	System	17 Oct 2020 17:03:38
User entered 'Yes (Y)'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248' User entered '97.3'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248'	System	17 Oct 2020 17:03:38
User entered 'Yes (Y)'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 05:50:18
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with, please see conmeds' (Site from System).	Frances Saubon (b) (4)	22 Oct 2020 14:51:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Oct 2020 17:03:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248'	System	17 Oct 2020 17:03:38
User entered '1'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248' User entered '0'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:03:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '3d394075-d55a-4060-928d-6e819de39248'	System	17 Oct 2020 17:03:38
User entered '17 Oct 2020 12:03'	System	17 Oct 2020 17:03:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 4'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered 'Yes (Y)'	System	18 Oct 2020 21:19:46
	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:35', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered '96.8'	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f'	System	18 Oct 2020 21:19:46
User entered 'No (N)'	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '9157e7f2-d39c-4467-82f3-afe67c3b050f' User entered '18 Oct 2020 16:19'	System	18 Oct 2020 21:19:46
	System	18 Oct 2020 21:19:46

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 5'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d'	System	20 Oct 2020 03:52:52
User entered 'Yes (Y)'	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d' User entered '97.0'	System	20 Oct 2020 03:52:52
	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d'	System	20 Oct 2020 03:52:52
User entered 'No (N)'	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'c0bd7a6f-b7e6-4a99-8d57-e16ae237be3d' User entered '19 Oct 2020 22:52'	System	20 Oct 2020 03:52:52
	System	20 Oct 2020 03:52:52

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 6'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b'	System	21 Oct 2020 04:32:57
User entered 'Yes (Y)'	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b' User entered '97.8'	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b'	System	21 Oct 2020 04:32:57
User entered 'No (N)'	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:32:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'aeaa420e-2725-45a1-8c90-5344db6e159b' User entered '20 Oct 2020 23:32'	System	21 Oct 2020 04:32:57
	System	21 Oct 2020 04:32:57

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 7'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a'	System	22 Oct 2020 03:20:53
User entered 'Yes (Y)'	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:40', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a'	System	22 Oct 2020 03:20:53
User entered '97.8'	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a'	System	22 Oct 2020 03:20:53
User entered 'No (N)'	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:20:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'bb14cfd7-042a-4b70-9f2d-43cf6fd6a15a'	System	22 Oct 2020 03:20:53
User entered '21 Oct 2020 22:20'	System	22 Oct 2020 03:20:53

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0'	System	15 Oct 2020 15:26:04
User entered 'None (1)'	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0'	System	15 Oct 2020 15:26:04
User entered 'No (N)'	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0'	System	15 Oct 2020 15:26:04
User entered 'No (N)'	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:25:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered 'None (1)'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '271b1895-7bf4-4d79-a44c-d913be6065f0' User entered '15 Oct 2020 10:26'	System	15 Oct 2020 15:26:04
	System	15 Oct 2020 15:26:04

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 10:16'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:46'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:18', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b'	System	16 Oct 2020 07:02:37
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b'	System	16 Oct 2020 07:02:37
User entered 'No (N)'	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:01:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b'	System	16 Oct 2020 07:02:37
User entered 'Yes (Y)'	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered '20'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b'	System	16 Oct 2020 07:02:37
User entered 'None (1)'	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0a3ccf2c-5aa4-4701-91c9-8e7c3506945b' User entered '16 Oct 2020 02:02'	System	16 Oct 2020 07:02:37
	System	16 Oct 2020 07:02:37

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 13:41'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 2'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:20:58', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3'	System	16 Oct 2020 18:22:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:21:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3'	System	16 Oct 2020 18:22:22
User entered 'No (N)'	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:21:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3'	System	16 Oct 2020 18:22:22
User entered 'Yes (Y)'	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:21:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered '76'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:04', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3'	System	16 Oct 2020 18:22:22
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'd19f29dc-9230-4d8e-afcd-a0459defc4a3' User entered '16 Oct 2020 13:22'	System	16 Oct 2020 18:22:22
	System	16 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 3'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:00:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:00:41', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered 'Yes (Y)'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered '100'	System	17 Oct 2020 17:01:49
	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered 'Yes (Y)'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered '125'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:38', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc'	System	17 Oct 2020 17:01:49
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e693a930-0d43-47f3-b86b-2babfb9dacfc' User entered '17 Oct 2020 12:01'	System	17 Oct 2020 17:01:49
	System	17 Oct 2020 17:01:49

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 4'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d'	System	18 Oct 2020 21:20:52
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:19:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d'	System	18 Oct 2020 21:20:52
User entered 'Yes (Y)'	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:15', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered '64'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d'	System	18 Oct 2020 21:20:52
User entered 'Yes (Y)'	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered '55'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:44', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d'	System	18 Oct 2020 21:20:52
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02b663bc-03e6-4af2-8d62-2f5f78797c7d' User entered '18 Oct 2020 16:20'	System	18 Oct 2020 21:20:52
	System	18 Oct 2020 21:20:52

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 5'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:52:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b'	System	20 Oct 2020 03:54:19
User entered 'Does not interfere with activity (2)'	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:53:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered 'Yes (Y)'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered '50'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b'	System	20 Oct 2020 03:54:19
User entered 'Yes (Y)'	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered '50'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b'	System	20 Oct 2020 03:54:19
User entered 'None (1)'	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '02aa32cc-0ccb-4245-bc49-b7188f917b3b' User entered '19 Oct 2020 22:54'	System	20 Oct 2020 03:54:19
	System	20 Oct 2020 03:54:19

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 6'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61'	System	21 Oct 2020 04:33:53
User entered 'Does not interfere with activity (2)'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:26', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61'	System	21 Oct 2020 04:33:53
User entered 'Yes (Y)'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered '40'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61'	System	21 Oct 2020 04:33:53
User entered 'Yes (Y)'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:43', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61' User entered '25'	System	21 Oct 2020 04:33:53
	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:46', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61'	System	21 Oct 2020 04:33:53
User entered 'None (1)'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '05c169c8-58fb-41cb-a6bd-2ce4185b3c61'	System	21 Oct 2020 04:33:53
User entered '20 Oct 2020 23:33'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 7'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'None (1)'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:16', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db'	System	22 Oct 2020 03:21:51
User entered 'Yes (Y)'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered '35'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'Yes (Y)'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered '20'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered 'None (1)'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'fc35cc5f-fe99-4e8c-a7e0-57a6b96369db' User entered '21 Oct 2020 22:21'	System	22 Oct 2020 03:21:51
	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:10', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'None (0)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered 'No (N)'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-15T10:26:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '1fe659f3-4485-4b01-9c90-4cb10333c782'	System	15 Oct 2020 15:26:32
User entered '15 Oct 2020 10:26'	System	15 Oct 2020 15:26:32

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 10:16'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:46'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'No interference with activity (1)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:02:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'None (0)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'None (0)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'None (0)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'None (0)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:22', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'None (0)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20'	System	16 Oct 2020 07:03:34
User entered 'No (N)'	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T02:03:32', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'f49c8327-28c2-4091-8b03-3e1bd83c5f20' User entered '16 Oct 2020 02:03'	System	16 Oct 2020 07:03:34
	System	16 Oct 2020 07:03:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 13:41'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 2'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:33', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:45', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'Some interference with activity (2)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:51', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'None (0)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'None (0)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:22:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'None (0)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:23:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'None (0)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:23:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74'	System	16 Oct 2020 18:23:14
User entered 'No (N)'	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-16T13:23:12', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '0e691a2c-d6eb-4d49-a48a-3528c1a83e74' User entered '16 Oct 2020 13:23'	System	16 Oct 2020 18:23:14
	System	16 Oct 2020 18:23:14

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 3'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:01:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:06', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'None (0)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:09', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'None (0)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:11', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'None (0)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'None (0)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961'	System	17 Oct 2020 17:02:30
User entered 'Yes (Y)'	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-17T12:02:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00305dac-b44c-4038-9e05-9f96be3c2961' User entered '17 Oct 2020 12:02'	System	17 Oct 2020 17:02:30
	System	17 Oct 2020 17:02:30

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 4'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:53', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'No interference with activity (1)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'None (0)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'None (0)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:20:59', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'None (0)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:01', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'None (0)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:03', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered 'None (0)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:10', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa'	System	18 Oct 2020 21:21:19
User entered 'No (N)'	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-18T16:21:14', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'b68eb26b-127d-43ee-9ca3-9bb735268daa' User entered '18 Oct 2020 16:21'	System	18 Oct 2020 21:21:19
	System	18 Oct 2020 21:21:19

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 5'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a'	System	20 Oct 2020 03:55:05
User entered 'None (0)'	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a'	System	20 Oct 2020 03:55:05
User entered 'None (0)'	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a' User entered 'None (0)'	System	20 Oct 2020 03:55:05
	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a'	System	20 Oct 2020 03:55:05
User entered 'None (0)'	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:36', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a'	System	20 Oct 2020 03:55:05
User entered 'None (0)'	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:54:52', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a'	System	20 Oct 2020 03:55:05
User entered 'No (N)'	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-19T22:55:03', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7fd13623-f08d-4204-b32b-3ed10339f85a'	System	20 Oct 2020 03:55:05
User entered '19 Oct 2020 22:55'	System	20 Oct 2020 03:55:05

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 6'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:55', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'None (0)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:33:57', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'None (0)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:00', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'None (0)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'None (0)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:05', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'None (0)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:34:07', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'None (0)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:45:50', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb'	System	21 Oct 2020 04:45:56
User entered 'No (N)'	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-20T23:45:54', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '14d19389-fb21-46f6-8efc-d9b441b227eb' User entered '20 Oct 2020 23:45'	System	21 Oct 2020 04:45:56
	System	21 Oct 2020 04:45:56

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 14:57:38
User entered 'Day 7'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:21:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:08', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:17', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:20', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:23', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'None (0)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered 'No (N)'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-21T22:22:31', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '71dfdba9-d164-4098-b2ef-81139404f542'	System	22 Oct 2020 03:22:34
User entered '21 Oct 2020 22:22'	System	22 Oct 2020 03:22:34

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 14:57:38

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 04:33:53
User entered 'Day 8'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:01:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:21:47', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '59a1a704-5597-4a86-b246-2a6b19c2a94f'	System	22 Oct 2020 18:21:58
User entered 'No (N)'	System	22 Oct 2020 18:21:58

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:21:56', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '59a1a704-5597-4a86-b246-2a6b19c2a94f' User entered '22 Oct 2020 13:21'	System	22 Oct 2020 18:21:58
	System	22 Oct 2020 18:21:58

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 04:33:53
User entered 'Day 8'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:02', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b932203-7f17-47ac-aa96-4e2caefc485a'	System	22 Oct 2020 18:22:22
User entered 'Yes (Y)'	System	22 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:13', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b932203-7f17-47ac-aa96-4e2caefc485a' User entered '25'	System	22 Oct 2020 18:22:22
	System	22 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:21', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '7b932203-7f17-47ac-aa96-4e2caefc485a' User entered '22 Oct 2020 13:22'	System	22 Oct 2020 18:22:22
	System	22 Oct 2020 18:22:22

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 03:21:51
User entered 'Day 9'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:25', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e3ee5167-511b-4239-8ebc-30254a27a088'	System	23 Oct 2020 19:21:32
User entered 'No (N)'	System	23 Oct 2020 19:21:32

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:29', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'e3ee5167-511b-4239-8ebc-30254a27a088'	System	23 Oct 2020 19:21:32
User entered '23 Oct 2020 14:21'	System	23 Oct 2020 19:21:32

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 04:33:53
User entered 'Day 8'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '004b8aa7-6d8f-4aae-802b-ff1f5796bdd1'	System	22 Oct 2020 18:22:31
User entered 'No (N)'	System	22 Oct 2020 18:22:31

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-22T13:22:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '004b8aa7-6d8f-4aae-802b-ff1f5796bdd1' User entered '22 Oct 2020 13:22'	System	22 Oct 2020 18:22:31
	System	22 Oct 2020 18:22:31

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 04:33:53

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 03:21:51
User entered 'Day 9'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

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 (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00b0a97c-6ac0-4383-90b1-0a507d3abada' User entered 'No (N)'	System	23 Oct 2020 19:21:42

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-10-23T14:21:37', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '00b0a97c-6ac0-4383-90b1-0a507d3abada' User entered '23 Oct 2020 14:21'	System	23 Oct 2020 19:21:42
	System	23 Oct 2020 19:21:42

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 03:21:51

US3322329

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:01:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 03:21:51

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:57

US3322329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 14:15:43

US3322329

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 14:15:43

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:01

US3322329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 15:10:03

US3322329

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 15:10:03

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:31

US3322329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Nov 2020 17:39:22

US3322329

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 17:39:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	17 Nov 2020 16:54:52

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '09:30'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '17 Nov 2020 09:30'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 14:32:36
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per source' (Site from System).	Frances Saubon (b) (4)	17 Nov 2020 17:13:24
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Nov 2020 16:57:22
User entered '96.6' F	Moez Talpur (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '17'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Nov 2020 16:57:22

US3322329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:24

US3322329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:24

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:24'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered '17 Nov 2020 10:24'	System	17 Nov 2020 16:58:37

US3322329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	17 Nov 2020 16:58:45

US3322329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 16:58:45

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 64'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-12T09:07:19', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '513ea189-1891-4540-ac53-a431a61c802a' User entered 'No (N)'	System	12 Nov 2020 15:07:32
	System	12 Nov 2020 15:07:32

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-12T09:07:24', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '513ea189-1891-4540-ac53-a431a61c802a' User entered 'No (N)'	System	12 Nov 2020 15:07:32
	System	12 Nov 2020 15:07:32

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-12T09:07:27', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '513ea189-1891-4540-ac53-a431a61c802a' User entered '12 Nov 2020 09:07:27'	System	12 Nov 2020 15:07:32
	System	12 Nov 2020 15:07:32

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '12 Nov 2020 00:01'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '16 Nov 2020 23:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered 'Day 71'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-19T14:42:30', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '06e34833-2611-4a1d-9a36-b6a67149d9fb'	System	19 Nov 2020 20:42:52
User entered 'No (N)'	System	19 Nov 2020 20:42:52

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-19T14:42:34', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '06e34833-2611-4a1d-9a36-b6a67149d9fb'	System	19 Nov 2020 20:42:52
User entered 'No (N)'	System	19 Nov 2020 20:42:52

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-19T14:42:48', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: '06e34833-2611-4a1d-9a36-b6a67149d9fb' User entered '19 Nov 2020 14:42:48'	System	19 Nov 2020 20:42:52
	System	19 Nov 2020 20:42:52

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '19 Nov 2020 00:01'	System	12 Sep 2020 17:10:21

US3322329

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 17:10:21
User entered '23 Nov 2020 23:59'	System	12 Sep 2020 17:10:21

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Nov 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Nov 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Nov 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Nov 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-23T06:45:28', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ba4144a5-c120-459c-8923-9ffa53c8ce07'	System	23 Nov 2020 12:45:52
User entered 'No (N)'	System	23 Nov 2020 12:45:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-23T06:45:42', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ba4144a5-c120-459c-8923-9ffa53c8ce07'	System	23 Nov 2020 12:45:52
User entered 'No (N)'	System	23 Nov 2020 12:45:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D4391D5-B8DD-404D-9C5D-74BF6C6C8437)', Time: '2020-11-23T06:45:49', User OID: 'PatientReportedOutcome (US3322329)', ODM File OID: 'ba4144a5-c120-459c-8923-9ffa53c8ce07'	System	23 Nov 2020 12:45:52
User entered '23 Nov 2020 06:45:49'	System	23 Nov 2020 12:45:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 08:01:52

US3322329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:01:52
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 08:01:52

US3322329

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:05
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:06:29

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:09
User entered 'USA-US060-2020-mRNA-1273-P301000006'	System	22 Oct 2020 18:43:06
User entered 'New'	(b) (4), (b) (6)	22 Oct 2020 18:43:06

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling face, LLT: Facial swelling - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 20:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 20:10:40
Data point term sent to Coder	System	21 Oct 2020 20:09:47
User entered 'Facial Swelling'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '17 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'No (N)' reason for change: New Information	Frances Saubon (b) (4)	30 Oct 2020 22:23:45
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 17:55:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:25
Comment added 'Query "Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct" was inadvertently closed, site will reflect data changes once available.'	Frances Saubon (b) (4)	30 Oct 2020 22:27:39
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4)	30 Oct 2020 22:25:15
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Frances Saubon (b) (4)	30 Oct 2020 22:24:02
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Oct 2020 22:23:45
User entered '22 Oct 2020' reason for change: New Information	Frances Saubon (b) (4)	30 Oct 2020 22:23:45
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:57:33
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Oct 2020 20:19:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Oct 2020 20:08:50
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '1' reason for change: Data Entry Error	Blessing Felix-Okoroji	21 Oct 2020 20:19:03
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Related (RELATED)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '1'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:15:31
DataPoint Un-verified.	(b) (4)	13 Nov 2020 20:22:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Elisa Moralez (b) (4)	13 Nov 2020 20:22:52
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4)	21 Oct 2020 20:08:50
	(b) (4)	

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:05:51
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:15:30
User closed query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.' (Site from Safety). Query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.'	(b) (4), (b) (6)	09 Nov 2020 15:27:52
Query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.'	Frances Saubon (b) (4)	07 Nov 2020 03:37:54
Query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.'	(b) (4)	
Comment added 'The IP is believed to have triggered an inflammatory response de novo or potentiated an underlying microscopic inflammatory response. We will contact subject again for further details and request medical records. Once further information is available, SAE will be updated.'	Frances Saubon (b) (4)	03 Nov 2020 15:35:11
Comment added 'Since the subject developed facial swelling almost two weeks after the procedure and only 2 days after receiving IP injection, the temporal relationship provides reasonable probability of causal relationship between the subject's facial swelling and receipt of IP.'	Frances Saubon (b) (4)	03 Nov 2020 15:34:50
Comment added 'CONTINUATION: However, I also believe if the facial swelling was solely due to the cosmetic procedure, it would have occurred before IP administration on 15 OCT 2020.'	Frances Saubon (b) (4)	03 Nov 2020 15:34:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 15:31:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 15:31:50
User entered 'SAE term: Facial swelling; Intensity: Severe; Causality: Considered IP related given it occurred on Day 3 of observation period post-vaccination. The prior cosmetic procedure believed to have been a contributing factor but not the cause since the procedure was almost 2 weeks before the facial swelling. A safety call was made on 20 OCT 2020 due to patient reporting grade 3 injection site swelling. Subject confirmed experiencing injection site swelling/hardness measuring 125mm on day 3 which came down to 55mm by day 4. She experienced mild deltoid tenderness but did not have any trouble moving the affected arm. During this safety call, the subject reported receiving medical attention on 17 October 2020 due to facial swelling. Patient stated she got dermal filler (Voluma -crosslinked hyaluronic acid) cosmetic injections in cheeks on 02 Oct 2020 prior to receiving second IP. It was a planned procedure, and she forgot to mention it when she came onsite for her second vaccine on 15 OCT 2020. During her visit 2, the physical exam was normal including skin. Patient stated she developed bilateral facial swelling (left greater than right) the night of 17 Oct 2020. She contacted the doctor that did the cosmetic procedure, and she was prescribed Prednisolone for 5 days. She took prednisolone 25mg on 17 Oct 2020 at 10 am and prednisolone 40mg daily thereafter. On 20 Oct 2020, the facial swelling was almost completely resolved with only minimal swelling under the left eye. The reason she called her doctor and the reason for treatment with prednisolone was the facial swelling not IP injection site swelling. Facial swelling is a potential side-effect of Voluma dermal filler topical injections, and I believe the injection of dermal filler was a contributing factor to the patient developing facial swelling.' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 15:31:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 15:27:09
DataPoint Un-verified.	Frances Saubon (b) (4)	03 Nov 2020 15:27:09
	(b) (4)	
User entered empty; reason for change New Information	Frances Saubon (b) (4)	03 Nov 2020 15:27:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 22:05:51
	(b) (4), (b) (6)	30 Oct 2020 21:57:44
User opened query 'PV Query: Please provide any clinical assessment/notes concerning the subject's facial swelling from the healthcare provider who prescribed treatment for the condition with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until records have been provided. If the records cannot be obtained, please state so in your response.' (Site from Safety).		
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 20:21:22
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Oct 2020 20:21:22

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'per physician "Considered IP related given it occurred on Day 3 of observation period post-vaccination. A safety call was made on 20 Oct 2020 due to patient reporting grade 3 injection site swelling. Subject confirmed experiencing injection site swelling/hardness measuring 125mm on day 3 which came down to 55mm by day 4. She experienced mild deltoid tenderness but did not have any trouble moving the affected arm. During safety call, the subject reported receiving medical attention 17 Oct 2020 due to facial swelling. Patient stated she got dermal filler cosmetic injections in cheeks on 02 Oct 2020 prior to receiving second IP. It was a planned procedure, and she forgot to mention it when she came onsite for her second vaccine on 15 Oct 2020. During her visit 2, the physical exam was normal including skin. Patient stated she developed bilateral facial swelling (left greater than right) the night of 17 Oct 2020. She contacted the doctor that did the cosmetic procedure, and she was prescribed Prednisolone for 5 days. She took prednisolone 25 mg on 17 Oct 2020 at 10 am and prednisolone 40mg daily thereafter. On 20 Oct 2020, the facial swelling was almost completely resolved with only minimal swelling under the left eyes. The reason she called her doctor and the reason for treatment with prednisolone was the facial swelling not IP injection site swelling. Facial swelling is a potential side-effect of Voluma dermal filler topical injections and I believe the injection of dermal filler was a contributing factor to the patient developing facial swelling. However, I also believe if the facial swelling was solely due to the cosmetic procedure, it would have occurred before IP administration on 15 Oct 2020. Since subject developed facial swelling almost two weeks after the procedure and only 2 days after IP injection, the temporal relationship provides reasonable probability of causal relationship between the subject's facial swelling and receipt of IP..." reason for change: Per Query Resolution	Elisa Morales (b) (4)	21 Oct 2020 20:21:22

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Oct 2020 20:08:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 20:08:50

US3322329

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 20:08:50

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:02

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:38:14
User closed query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:29:56
Query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'naproxen is entered in conmeds toward this entry' (Site from DM).	Elisa Moralez (b) (4)	23 Oct 2020 15:22:03
User opened query 'Per CDM: According to a "Diary Dose 2", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 05:50:51
	(b) (4), (b) (6)	17 Sep 2020 21:22:29

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:53:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:53:21
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 16:52:46 30 Oct 2020 16:51:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:48:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:48:46
Data point term sent to Coder User entered 'NAPROXEN'	System (b) (4), (b) (6)	17 Sep 2020 21:33:43 17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORE MUSCLES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORE MUSCLES did not meet the AE reporting criteria ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:37:55
	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORE MUSCLES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORE MUSCLES did not meet the AE reporting criteria ' answered with 'this does not meet the requirements for AE reporting and was reported less than 4 days after IP from vaccine 2' (Site from DM). User entered 'muscle pain' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 16:52:38
	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 16:51:51

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORE MUSCLES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORE MUSCLES did not meet the AE reporting criteria ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:51:09
User entered 'SORE MUSCLES'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '500'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once (ONCE)'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 21:32:41

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:55:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:55:07
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Data point term sent to Coder	System	02 Nov 2020 16:44:33
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:43:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:26:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:26:41
Data point term sent to Coder	System	26 Sep 2020 19:08:54
User entered 'Estradiol pellet'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:36:43
Query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM). User entered 'post menopausal' reason for change: New Information	Elisa Moralez (b) (4)	02 Nov 2020 16:44:06
User opened query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM). User entered 'Hormone replacement therapy'	Elisa Moralez (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '25'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'every 3 months'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'un UNK 2014'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:08:04

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:41:28
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
Data point term sent to Coder	System	02 Nov 2020 16:44:32
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 16:44:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:35:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:35:37
Data point term sent to Coder	System	26 Sep 2020 19:10:55
User entered 'Testosterone Pellet'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:38:11
Query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM). User entered 'post menopausal' reason for change: New Information	Elisa Moralez (b) (4)	02 Nov 2020 22:03:38
User opened query 'Per DM CLR : Please note that Con Med indication should reflect a medical condition instead of what the drug does. Please review and update the Con Med indication with the corresponding AE or Med History eCRF so there is an appropriate match. ' (Site from DM). User entered 'Hormone replacement therapy'	(b) (4)	02 Nov 2020 16:44:22
	(b) (4), (b) (6)	02 Nov 2020 16:44:12
	(b) (4), (b) (6)	30 Oct 2020 10:51:21
	Elisa Moralez (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '87.5'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'every 3 months'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:39
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'un UNK 2014'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 19:10:39

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
Data point term sent to Coder	System	21 Oct 2020 19:57:15
User entered 'Prednisolone'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Facial Swelling'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '25'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '17 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '17 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:56:25
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:55:36
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 19:10:53

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:08:35
Data point term sent to Coder	System	21 Oct 2020 19:57:17
User entered 'Prednisolone'	Elisa Morales (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Facial Swelling'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '40'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:48
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	21 Oct 2020 19:56:48
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4)	21 Oct 2020 19:56:48
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '18 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:56:48

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:52:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:52:31
Data point term sent to Coder	System	21 Oct 2020 19:58:23
User entered 'Voluma (crosslinked hyaluronic acid)'	Elisa Morales (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Cosmetic Procedure'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '1'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'mL (mL)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered '02 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 19:57:22
	(b) (4)	

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:03:38
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:57:22

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:33

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Dermal filler injection'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:02

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered 'cosmetic'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 19:57:57

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered '22/Oct/2020 18:43'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:02

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)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '02/Nov/2020 22:15'	System	02 Nov 2020 22:15:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:01:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:39:03
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 22:15:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '03/Nov/2020 15:39'	System	03 Nov 2020 15:39:15

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:01:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 15:40:42
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 15:39:15

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '09/Nov/2020 10:40'	System	09 Nov 2020 15:40:20

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:01:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:17:28
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 15:40:20

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'USA-US060-2020-MRNA-1273-P301000006'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'No (N)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Yes (Y)'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Veronica'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Fragoso'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '6550 Mapleridge Street'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'Houston'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered 'TX'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 18:43:23
User entered '77081'	System	22 Oct 2020 18:43:06

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 22:14:51
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:06:48
User entered 'US'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:01:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	16 Nov 2020 14:17:45
User entered '4'	System	09 Nov 2020 15:40:20
User entered '3'	System	03 Nov 2020 15:39:15
User entered '2'	System	02 Nov 2020 22:15:06
User entered '1'	System	22 Oct 2020 18:43:30

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:01:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered '16/Nov/2020 09:17'	System	16 Nov 2020 14:17:45

US3322329

Folder: SAE USA-US060-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:01:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:14
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:17:45