

US3252516 (Prod: Centex Studies Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:52:19

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US3252516

Form: Participant Creation

Generated On: 26 Nov 2020 10:52:19

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:52:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:52:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

Condition	TYPE II DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

Condition	LIVER CIRRHOSIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:28 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:28
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	164 lb
BMI (<i>xxx.x</i>)	25.73974 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

CURRENTLY NOT WORKING.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 146657

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

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

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

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

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

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

Liver Disease Yes ☒ No ☐

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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)	21 SEP 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:28
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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)	21 SEP 2020
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 13:29
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	120 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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)	21 SEP 2020
What was the treatment time? (00:00-23:59)	12:59 (24 HR)
Treatment Date and Time (derived)	21 SEP 2020 12:59
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	21 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:11 (24 HR)
Collection date and time (derived)	21 SEP 2020 12:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:19

Collection date (<i>dd MMM yyyy</i>)			21 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	12:07	21 SEP 2020 12:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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

97.8 °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 SEP 2020 13:47

PC Open Date & Time

21 SEP 2020 13:19

PC Close Date & Time

21 SEP 2020 15:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 19:09

PC Open Date & Time

21 SEP 2020 16:44

PC Close Date & Time

22 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

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

97.8 °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

22 SEP 2020 20:47

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:40

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:48

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 01:03

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 15:33

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

28 SEP 2020 04:07

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 13:48

PC Open Date & Time

21 SEP 2020 13:19

PC Close Date & Time

21 SEP 2020 15:49

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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

21 SEP 2020 19:09

PC Open Date & Time

21 SEP 2020 16:44

PC Close Date & Time

22 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:48

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 19:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

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

24 SEP 2020 19:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

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

26 SEP 2020 01:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

26 SEP 2020 15:34

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

28 SEP 2020 04:07

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 13:48
PC Open Date & Time	21 SEP 2020 13:19
PC Close Date & Time	21 SEP 2020 15:49

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 19:10
PC Open Date & Time	21 SEP 2020 16:44
PC Close Date & Time	22 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:48
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:41
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 19:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 01:04
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:35
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 04:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

Was Contact Attempted?

Yes ☒

No ☐

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

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

Was Contact Attempted?

Yes ☒

No ☐

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

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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)	20 OCT 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 11:19
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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)	20 OCT 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 12:21
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3252516

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

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.

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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)	20 OCT 2020
What was the treatment time? (00:00-23:59)	11:51 (24 HR)
Treatment Date and Time (derived)	20 OCT 2020 11:51
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

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	20 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:43 (24 HR)
Collection date and time (derived)	20 OCT 2020 11:43

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:19

Collection date (dd MMM yyyy)			20 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:24	20 OCT 2020 11:24
Nasopharyngeal Swab 2	No		

US3252516

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 20 OCT 2020 12:11

PC Close Date & Time 20 OCT 2020 14:41

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 20 OCT 2020 15:36

PC Close Date & Time 21 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 11:39

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 09:58

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

25 OCT 2020 07:36

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 09:46

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 08:05

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

20 OCT 2020 12:11

PC Close Date & Time

20 OCT 2020 14:41

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

20 OCT 2020 15:36

PC Close Date & Time

21 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

26 OCT 2020 09:46

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

27 OCT 2020 08:04

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 12:11

PC Close Date & Time

20 OCT 2020 14:41

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 OCT 2020 15:36

PC Close Date & Time

21 OCT 2020 11:59

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		22 OCT 2020 12:00
<hr/>		
PC Close Date & Time		23 OCT 2020 11:59
<hr/>		

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		23 OCT 2020 12:00
<hr/>		
PC Close Date & Time		24 OCT 2020 11:59
<hr/>		

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		24 OCT 2020 12:00
<hr/>		
PC Close Date & Time		25 OCT 2020 11:59
<hr/>		

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

		Yes <input type="checkbox"/>
PC Time stamp	26 OCT 2020 09:47	
PC Open Date & Time	25 OCT 2020 12:00	
PC Close Date & Time	26 OCT 2020 11:59	

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 ☒

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 08:05
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

Was Contact Attempted?

Yes ☒

No ☐

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

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

Was Contact Attempted?

Yes ☒

No ☐

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

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252516

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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>)	10:31 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 10:31
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252516

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

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.

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

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>)	10:53 (24 HR)
Collection date and time (derived)	17 NOV 2020 10:53

US3252516

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 61

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 16:23:12

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 159

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 <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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 <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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	13 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 MAR 2022 00:01
Patient Cloud Close Date & Time	27 MAR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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 ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	07 AUG 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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="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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 761

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

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

No ☐

Yes ☐

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01
Patient Cloud Close Date & Time	13 NOV 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

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

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3252516

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252516

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:52:19

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"/>

US3252516

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:52:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252516

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:52:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

AEID	USA-US108-2020-MRNA-1273-P30 1000004
Adverse event	COLITIS
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)	30 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	30 SEP 2020 00:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	08 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	329 of 1543

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

DURING D22 SAFETY PHONE
CALL ON 12-OCT-2020 MR.
SUBJECT REPORTED A RECENT
HOSPITALIZATION. HE
REPORTS BEING DIAGNOSED
WITH COLITIS ON 30-SEP-2020
AND WAS HOSPITALIZED FOR
A TOTAL OF NINE DAYS.
PATIENT WAS REPORTEDLY
DISCHARGED FROM VALLEY
REGIONAL MEDICAL CENTER
ON 08-OCT-2020 AND WAS
GIVEN A PRESCRIPTION FOR
METRONIDAZOLE 500 MG TID
AND LEVOFLOXACIN 500 MG
ONCE A DAY. PATIENT
STARTED BOTH OF THESE
MEDICATIONS YESTERDAY ON
11-OCT-2020. PATIENT WAS
SENT A MEDICAL RELEASE
FORM VIA EMAIL IN ORDER TO
OBTAIN RECORDS FROM HIS
HOSPITALIZATION. WILL
CONTINUE TO UPDATE
INFORMATION AS IT BECOMES
AVAILABLE.

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

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

AEID	USA-US108-2020-MRNA-1273-P30 1000004
Adverse event	PNEUMONIA
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)	30 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	30 SEP 2020 00:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	332 of 1543

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

DURING D29 VISIT, PATIENT
REPORTED HE WAS
DIAGNOSED WITH PNEUMONIA
ALONG WITH COLITIS AND
WAS ADMITTED TO THE
HOSPITAL. COLITIS WAS
ALREADY RECORDED ON
SAFETY CALL HOWEVER HE
DID NOT REPORT THE
PNEUMONIA. MEDICAL
RELEASE RECORD HAS BEEN
SIGNED AND UPDATES WILL BE
PROVIDED ONCE MORE
INFORMATION IS AVAILABLE.

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

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:52:19

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

Yes ☒

No ☐

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

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

	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 2010	
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"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

Name of Medication	JANUVIA
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	TYPE II DIABETES MELLITUS
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input 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 checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

	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 2010
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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

Name of Medication	METRONIDAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COLITIS
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 checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

	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)		11 OCT 2020
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

Name of Medication	LEVOFLOXACIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COLITIS
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 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"/>

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

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)	11 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"/>

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:52:19

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3252516

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:52:19

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

US3252516

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:52:19

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)	
Reason for discontinuation	<div>AE (specify) <input type="checkbox"/></div> <div>SAE (specify) <input type="checkbox"/></div> <div>Complete <input type="checkbox"/></div> <div>Death <input type="checkbox"/></div> <div>Lost To Follow-up <input type="checkbox"/></div> <div>Physician decision (specify) <input type="checkbox"/></div> <div>Pregnancy <input type="checkbox"/></div> <div>Protocol deviation (specify) <input type="checkbox"/></div> <div>Study Terminated By Sponsor <input type="checkbox"/></div> <div>Withdrawal of consent by participant (specify) <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>
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	<div>Adverse event <input type="checkbox"/></div> <div>Unknown <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>
If main cause of death is Other, specify	
Date of death (<i>dd MMM yyyy</i>)	
Was autopsy performed?	<div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div> <div>Unknown <input type="checkbox"/></div>

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:19

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	13/OCT/2020 10:00
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

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:19

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 20:14
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

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:52:19

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 20:30
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

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:52:19

SAEID	USA-US108-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/OCT/2020 14:19
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

US3252516 (Prod: Centex Studies Inc)

US3252516

Form: Participant Creation

Generated On: 26 Nov 2020 10:52:19

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3252516'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Sep 2020 16:45:31

US3252516

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:07:37

US3252516

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Sep 2020 16:45:32

US3252516

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 17:07:37

US3252516

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Sep 2020 17:07:37

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered (b) (6) 1980'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Sep 2020 16:45:33

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Age](#)

Audit	User	Time (GMT)
User entered '40'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '40'	System	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[White](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

If race is Other, specify

Audit	User	Time (GMT)
User entered 'Hispanic'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:52:19

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:08:03

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

If reason for screen fail is [Other](#), specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 17:11:22

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Sep 2020 16:45:32

US3252516

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:52:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:52:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:12

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:10:49
Data point term sent to Coder	System	22 Sep 2020 05:10:28
User entered 'Type II Diabetes Mellitus'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '2010'	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:09:52

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:10:49
Data point term sent to Coder	System	22 Sep 2020 05:10:28
User entered 'Hypertension'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '2010'	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:10:27

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Liver cirrhosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:11:50
Data point term sent to Coder	System	22 Sep 2020 05:11:29
User entered 'Liver Cirrhosis'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '2010'	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:11:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '11:28'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:28'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '67' in	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
DataPoint set to visible.	(b) (4) System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '164' lb	Nancy Torrence (b) (4)	22 Sep 2020 05:12:00
DataPoint set to visible.	(b) (4) System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '25.73974'	System	22 Sep 2020 05:12:00
DataPoint set to visible.	System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	22 Sep 2020 05:12:00
DataPoint set to visible.	System	21 Sep 2020 17:11:27

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 05:12:00

US3252516

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:32

US3252516

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:12:32

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

[Specify](#)

Audit	User	Time (GMT)
User entered 'Currently not working.'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '1'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:52:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:13:25

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Sep 2020 18:17:32

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Sep 2020 16:50:28

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '146657'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Sep 2020 16:50:28

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Sep 2020 16:50:28

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

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)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:14:30

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:14:30

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:14:30

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:14:30

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:14:30

US3252516

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:14:30
DataPoint set to visible.	(b) (4) System	21 Sep 2020 17:11:22

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '11:28'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:28'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Pulse (xxx)

Audit	User	Time (GMT)
User entered '85'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '16'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '105'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:52:19

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '13:29'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 13:29'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Pulse (xxx)

Audit	User	Time (GMT)
User entered '120'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '18'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '103'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 05:18:17

US3252516

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:37

US3252516

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:18:37

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '12:59'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 18:18:33

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:58:34
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Samples have been shipped. AWB Number: 917903344847' (Site from DM).	Uche Ehiemua (b) (4)	12 Oct 2020 16:35:50
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 21SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 19:08:00
User entered '21 Sep 2020'	Nancy Torrence (b) (4)	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Sep 2020 14:29:32
User entered '12:11' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 14:29:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 05:23:48
User entered 'UN:UN' (non-conformant).	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:11'	System	23 Sep 2020 14:29:32
User entered '21 Sep 2020 UN:UN' (non-conformant).	System	22 Sep 2020 05:23:48

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:07'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:07'	System	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 05:24:32

US3252516

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:24:37

US3252516

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:24:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9'	System	21 Sep 2020 18:47:20
User entered 'Yes (Y)'	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9' User entered '97.8'	System	21 Sep 2020 18:47:20
	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9'	System	21 Sep 2020 18:47:20
User entered 'No (N)'	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:17', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '2c54fee6-b4aa-42f8-ac47-f336a4bd90d9'	System	21 Sep 2020 18:47:20
User entered '21 Sep 2020 13:47'	System	21 Sep 2020 18:47:20

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 13:19'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:08:47', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f' User entered 'Yes (Y)'	System	22 Sep 2020 00:09:12
	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:08:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f'	System	22 Sep 2020 00:09:12
User entered '98.6'	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:02', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f'	System	22 Sep 2020 00:09:12
User entered 'No (N)'	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f595ed80-4147-49bb-8e98-38dabe60392f' User entered '21 Sep 2020 19:09'	System	22 Sep 2020 00:09:12
	System	22 Sep 2020 00:09:12

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 2'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:46:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5'	System	23 Sep 2020 01:47:37
User entered 'Yes (Y)'	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5'	System	23 Sep 2020 01:47:37
User entered '97.8'	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:14', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5'	System	23 Sep 2020 01:47:37
User entered 'No (N)'	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '24bdbded-03d4-4615-8d43-f6c9a85cbcd5'	System	23 Sep 2020 01:47:37
User entered '22 Sep 2020 20:47'	System	23 Sep 2020 01:47:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 3'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:31', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756'	System	24 Sep 2020 00:40:53
User entered 'Yes (Y)'	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:40', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756'	System	24 Sep 2020 00:40:53
User entered '98.9'	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756'	System	24 Sep 2020 00:40:53
User entered 'No (N)'	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'd9edef30-c0e9-455f-905e-707603644756'	System	24 Sep 2020 00:40:53
User entered '23 Sep 2020 19:40'	System	24 Sep 2020 00:40:53

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 4'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:31', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea' User entered 'Yes (Y)'	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:40', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea' User entered '98.1'	System	25 Sep 2020 00:49:00
	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:44', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea'	System	25 Sep 2020 00:49:00
User entered 'No (N)'	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:48:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '30eecf9b-a96a-40e6-a14b-55fbca6403ea' User entered '24 Sep 2020 19:48'	System	25 Sep 2020 00:49:00
	System	25 Sep 2020 00:49:00

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 5'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea'	System	26 Sep 2020 06:03:37
User entered 'Yes (Y)'	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea' User entered '98.1'	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:30', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea'	System	26 Sep 2020 06:03:37
User entered 'No (N)'	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:34', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f66b33a8-da8d-4abb-b618-bcfcabfe50ea' User entered '26 Sep 2020 01:03'	System	26 Sep 2020 06:03:37
	System	26 Sep 2020 06:03:37

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 6'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5'	System	26 Sep 2020 20:33:58
User entered 'Yes (Y)'	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5'	System	26 Sep 2020 20:33:58
User entered '96.4'	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:53', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5'	System	26 Sep 2020 20:33:58
User entered 'No (N)'	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:33:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'bcf48415-38a5-4fd0-9538-3464b7bc4ca5'	System	26 Sep 2020 20:33:58
User entered '26 Sep 2020 15:33'	System	26 Sep 2020 20:33:58

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 7'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered 'Yes (Y)'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered '98.3'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered 'No (N)'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:26', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0b87fbd8-d25e-4702-af2e-5af6dd9215a2'	System	28 Sep 2020 09:07:30
User entered '28 Sep 2020 04:07'	System	28 Sep 2020 09:07:30

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:30', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'None (1)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:33', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'No (N)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:36', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'No (N)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:47:47', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered 'None (1)'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:01', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9da3eb66-4ead-443e-847c-af02b46c6f6d'	System	21 Sep 2020 18:48:05
User entered '21 Sep 2020 13:48'	System	21 Sep 2020 18:48:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 13:19'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1'	System	22 Sep 2020 00:09:45
User entered 'None (1)'	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:28', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1'	System	22 Sep 2020 00:09:45
User entered 'No (N)'	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1'	System	22 Sep 2020 00:09:45
User entered 'No (N)'	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1'	System	22 Sep 2020 00:09:45
User entered 'None (1)'	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:43', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '78953a7a-2141-4a75-b47e-941cad3e05b1'	System	22 Sep 2020 00:09:45
User entered '21 Sep 2020 19:09'	System	22 Sep 2020 00:09:45

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 2'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1'	System	23 Sep 2020 01:48:13
User entered 'None (1)'	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1'	System	23 Sep 2020 01:48:13
User entered 'No (N)'	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered 'No (N)'	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:47:58', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1'	System	23 Sep 2020 01:48:13
User entered 'None (1)'	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:06', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '4a97ebdd-c25d-4eba-9289-61912db2f4e1' User entered '22 Sep 2020 20:48'	System	23 Sep 2020 01:48:13
	System	23 Sep 2020 01:48:13

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 3'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

[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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:40:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered 'None (1)'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde'	System	24 Sep 2020 00:41:19
User entered 'No (N)'	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde'	System	24 Sep 2020 00:41:19
User entered 'No (N)'	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde' User entered 'None (1)'	System	24 Sep 2020 00:41:19
	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:16', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7371380d-10d2-48d6-a613-6032cf580cde'	System	24 Sep 2020 00:41:19
User entered '23 Sep 2020 19:41'	System	24 Sep 2020 00:41:19

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 4'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:15', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1'	System	25 Sep 2020 00:49:36
User entered 'None (1)'	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1'	System	25 Sep 2020 00:49:36
User entered 'No (N)'	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1'	System	25 Sep 2020 00:49:36
User entered 'No (N)'	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:27', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1' User entered 'None (1)'	System	25 Sep 2020 00:49:36
	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '51ad5560-a9ab-48ce-b2fa-e18db7ac48c1' User entered '24 Sep 2020 19:49'	System	25 Sep 2020 00:49:36
	System	25 Sep 2020 00:49:36

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 5'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

[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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'None (1)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'No (N)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:53', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'No (N)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:03:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered 'None (1)'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:02', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b982bfe5-6a8f-46be-bfd8-719a73f030f0'	System	26 Sep 2020 06:04:05
User entered '26 Sep 2020 01:04'	System	26 Sep 2020 06:04:05

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 6'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'None (1)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'No (N)'	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'No (N)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered 'None (1)'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e542fbcf-b3ed-4815-b394-e3cc34b1abcf' User entered '26 Sep 2020 15:34'	System	26 Sep 2020 20:34:31
	System	26 Sep 2020 20:34:31

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 7'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:33', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'None (1)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'No (N)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:41', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'No (N)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:45', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered 'None (1)'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'df4a4035-e3f3-48f5-85ce-8285c3e5be5d'	System	28 Sep 2020 09:07:52
User entered '28 Sep 2020 04:07'	System	28 Sep 2020 09:07:52

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:07', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'None (0)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:17', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'None (0)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:23', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'None (0)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'None (0)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'None (0)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:34', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'None (0)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered 'No (N)'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T13:48:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '817048fd-7091-4526-88e7-9195d3c289f0'	System	21 Sep 2020 18:48:45
User entered '21 Sep 2020 13:48'	System	21 Sep 2020 18:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 13:19'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:52', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'None (0)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'None (0)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:09:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'None (0)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'None (0)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'None (0)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'None (0)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered 'No (N)'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-21T19:10:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'b62f766f-4646-49a0-a8b4-3a2edef7e48c'	System	22 Sep 2020 00:10:24
User entered '21 Sep 2020 19:10'	System	22 Sep 2020 00:10:24

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 16:44'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 2'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:14', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253'	System	23 Sep 2020 01:48:45
User entered 'None (0)'	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:17', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253'	System	23 Sep 2020 01:48:45
User entered 'None (0)'	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:27', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253'	System	23 Sep 2020 01:48:45
User entered 'None (0)'	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'None (0)'	System	23 Sep 2020 01:48:45
	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:33', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253' User entered 'No (N)'	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-22T20:48:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '84bd47ba-ca00-4a61-a7f0-86c533733253'	System	23 Sep 2020 01:48:45
User entered '22 Sep 2020 20:48'	System	23 Sep 2020 01:48:45

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 3'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:22', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b'	System	24 Sep 2020 00:41:55
User entered 'None (0)'	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b'	System	24 Sep 2020 00:41:55
User entered 'None (0)'	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:28', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b'	System	24 Sep 2020 00:41:55
User entered 'None (0)'	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b' User entered 'None (0)'	System	24 Sep 2020 00:41:55
	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b'	System	24 Sep 2020 00:41:55
User entered 'None (0)'	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b'	System	24 Sep 2020 00:41:55
User entered 'No (N)'	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-23T19:41:52', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '0a63cd3e-45d4-45a0-a567-ba017c8b5b8b'	System	24 Sep 2020 00:41:55
User entered '23 Sep 2020 19:41'	System	24 Sep 2020 00:41:55

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 4'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:50', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:54', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:49:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:50:06', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'None (0)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:50:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered 'No (N)'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-24T19:50:14', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'ae1409b2-38ef-4e35-8710-30d2fa833aa6'	System	25 Sep 2020 00:50:18
User entered '24 Sep 2020 19:50'	System	25 Sep 2020 00:50:18

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 5'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:16', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:27', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'None (0)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered 'No (N)'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T01:04:36', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '5e7d0b86-059e-48fa-a4e3-03b67c73055d' User entered '26 Sep 2020 01:04'	System	26 Sep 2020 06:04:39
	System	26 Sep 2020 06:04:39

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 6'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:44', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:49', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:34:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'None (0)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:13', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered 'No (N)'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-26T15:35:18', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc527ad4-758f-4680-9bfd-1e50563f2f5d'	System	26 Sep 2020 20:35:20
User entered '26 Sep 2020 15:35'	System	26 Sep 2020 20:35:20

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 18:18:33
User entered 'Day 7'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:54', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'None (0)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:07:57', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'None (0)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:03', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'None (0)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:06', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'None (0)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'None (0)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'None (0)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered 'No (N)'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-09-28T04:08:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'eb4b1604-6b4f-4401-8f18-c7a18a5346c3'	System	28 Sep 2020 09:08:27
User entered '28 Sep 2020 04:08'	System	28 Sep 2020 09:08:27

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 18:18:33

US3252516

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 18:18:33

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:37

US3252516

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	06 Oct 2020 02:44:43

US3252516

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 02:44:43

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:37:55

US3252516

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:38:01

US3252516

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 14:38:01

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	17 Nov 2020 05:22:37
User entered 'During D22 Safety Phone Call on 12-OCT-2020 Mr. (b) (6) reported a recent hospitalization. He reports being diagnosed with Colitis on 30-SEP-2020 and was hospitalized for a total of nine days. Patient was reportedly discharged from Valley Regional Medical Center on 08-OCT-2020 and was given a prescription for Metronidazole 500 mg TID and Levofloxacin 500 mg once a day. Patient started both of these medications yesterday on 11-OCT-2020. Patient was sent a medical release form via email in order to obtain records from his hospitalization. Will continue to update information as it becomes available.' (non-conformant).	(b) (4), (b) (6)	12 Oct 2020 18:54:46

US3252516

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:54:54

US3252516

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 18:54:54

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	20 Oct 2020 16:53:04

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '11:19'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:19'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '16'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '94'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '60'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:52:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '12:21'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:21'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '16'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '98'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '65'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:52:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 11:01:34

US3252516

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:58

US3252516

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:01:58

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '11:51'	Joanna Gurrola (b) (4) (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:51'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 16:54:12

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:43'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:43'	System	21 Oct 2020 11:02:42

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:52:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:24'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:24'	System	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 11:03:06

US3252516

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	21 Oct 2020 11:03:18

US3252516

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 11:03:18

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:11'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 14:41'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 15:36'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 2'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990'	System	22 Oct 2020 16:39:53
User entered 'Yes (Y)'	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:38', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990'	System	22 Oct 2020 16:39:53
User entered '98.5'	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:43', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990'	System	22 Oct 2020 16:39:53
User entered 'No (N)'	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-22T11:39:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7482b55f-03c3-4d07-a38e-9ef6317c7990'	System	22 Oct 2020 16:39:53
User entered '22 Oct 2020 11:39'	System	22 Oct 2020 16:39:53

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 3'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:57:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d'	System	23 Oct 2020 14:58:17
User entered 'Yes (Y)'	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:58:05', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d' User entered '98.7'	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:58:09', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d'	System	23 Oct 2020 14:58:17
User entered 'No (N)'	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-23T09:58:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'de058327-4c95-4e64-8416-a9409063167d' User entered '23 Oct 2020 09:58'	System	23 Oct 2020 14:58:17
	System	23 Oct 2020 14:58:17

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 4'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 5'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:37', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695'	System	25 Oct 2020 12:36:57
User entered 'Yes (Y)'	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:47', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695' User entered '98.3'	System	25 Oct 2020 12:36:57
	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:51', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695'	System	25 Oct 2020 12:36:57
User entered 'No (N)'	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-25T07:36:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '7e4076d4-77be-4ab0-adb2-2d5f0f636695' User entered '25 Oct 2020 07:36'	System	25 Oct 2020 12:36:57
	System	25 Oct 2020 12:36:57

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 6'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered 'Yes (Y)'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered '98.7'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:15', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered 'No (N)'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:20', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'e548a52e-799d-4255-b849-1b477587e896'	System	26 Oct 2020 14:46:23
User entered '26 Oct 2020 09:46'	System	26 Oct 2020 14:46:23

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 7'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:55', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928'	System	27 Oct 2020 13:05:13
User entered 'Yes (Y)'	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:04', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928' User entered '98.4'	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:08', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928'	System	27 Oct 2020 13:05:13
User entered 'No (N)'	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '624eb070-236c-4e44-8566-9f476bc59928' User entered '27 Oct 2020 08:05'	System	27 Oct 2020 13:05:13
	System	27 Oct 2020 13:05:13

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:11'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 14:41'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 15:36'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 2'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 3'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 4'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 5'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 6'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'None (1)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:38', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'No (N)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:42', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'No (N)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:48', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4'	System	26 Oct 2020 14:46:53
User entered 'None (1)'	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:50', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'dc7f0bb8-9a3a-460f-aa87-b3c5e37824c4' User entered '26 Oct 2020 09:46'	System	26 Oct 2020 14:46:53
	System	26 Oct 2020 14:46:53

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 7'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:21', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'None (1)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:24', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'No (N)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:28', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'No (N)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:34', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200'	System	27 Oct 2020 13:04:42
User entered 'None (1)'	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:04:40', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'a7fdf4e9-153d-425d-b832-8f9e45223200' User entered '27 Oct 2020 08:04'	System	27 Oct 2020 13:04:42
	System	27 Oct 2020 13:04:42

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:11'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 14:41'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 15:36'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 2'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 3'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 4'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 5'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 6'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:56', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2'	System	26 Oct 2020 14:47:39
User entered 'None (0)'	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:46:59', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2'	System	26 Oct 2020 14:47:39
User entered 'None (0)'	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:03', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2'	System	26 Oct 2020 14:47:39
User entered 'None (0)'	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:07', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered 'None (0)'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:10', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2'	System	26 Oct 2020 14:47:39
User entered 'None (0)'	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:13', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2'	System	26 Oct 2020 14:47:39
User entered 'None (0)'	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:30', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2'	System	26 Oct 2020 14:47:39
User entered 'Yes (Y)'	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-26T09:47:35', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '9a146ec8-6477-4eb7-96e5-b45eb223bdc2' User entered '26 Oct 2020 09:47'	System	26 Oct 2020 14:47:39
	System	26 Oct 2020 14:47:39

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 16:54:12
User entered 'Day 7'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:15', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:19', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:54', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:25', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:29', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca'	System	27 Oct 2020 13:06:01
User entered 'None (0)'	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:32', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'None (0)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:39', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered 'No (N)'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-10-27T08:05:58', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: 'f05fc127-3a64-4aba-b032-685d5b7658ca' User entered '27 Oct 2020 08:05'	System	27 Oct 2020 13:06:01
	System	27 Oct 2020 13:06:01

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 16:54:12

US3252516

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:52:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 16:54:12

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:43

US3252516

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Oct 2020 05:13:50

US3252516

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 05:13:50

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:46

US3252516

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:42:50

US3252516

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 02:42:50

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:52:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:39

US3252516

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	10 Nov 2020 20:04:46

US3252516

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 20:04:46

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:39:33

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:39:33

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:39:33

US3252516

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:52:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	18 Nov 2020 09:39:33

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '10:31'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '17 Nov 2020 10:31'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '82'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '15'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:52:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Nov 2020 09:40:27

US3252516

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:34

US3252516

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:52:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:34

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:48

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:48

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:53'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:48

US3252516

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '17 Nov 2020 10:53'	System	18 Nov 2020 09:40:48

US3252516

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:40:55

US3252516

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:52:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 09:40:55

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-22T16:23:00', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '43d42283-155a-4412-bd26-964ba137a3a3'	System	22 Nov 2020 22:23:14
User entered 'No (N)'	System	22 Nov 2020 22:23:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

Have you been exposed to someone with 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 (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-22T16:23:07', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '43d42283-155a-4412-bd26-964ba137a3a3'	System	22 Nov 2020 22:23:14
User entered 'No (N)'	System	22 Nov 2020 22:23:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CE5FE4FA-F055-47BF-B46D-D2628A6F5803)', Time: '2020-11-22T16:23:12', User OID: 'PatientReportedOutcome (US3252516)', ODM File OID: '43d42283-155a-4412-bd26-964ba137a3a3'	System	22 Nov 2020 22:23:14
User entered '22 Nov 2020 16:23:12'	System	22 Nov 2020 22:23:14

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 09:58:02

US3252516

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:52:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:58:02
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 09:58:02

US3252516

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:52:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:04:12
User entered 'No (N)'	Nancy Torrence (b) (4)	22 Sep 2020 05:29:28

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:29
User entered 'USA-US108-2020-mRNA-1273-P301000004'	System	13 Oct 2020 14:00:26
User entered 'New'	(b) (4), (b) (6)	13 Oct 2020 14:00:26

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:47:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:10:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:10:29
Data point term sent to Coder	System	12 Oct 2020 19:09:21
User entered 'Colitis'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:01:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 14:39:28
	(b) (4), (b) (6)	21 Nov 2020 00:02:07
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4)	18 Nov 2020 09:46:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 09:45:19
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 05:31:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:49:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:49:08
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:09:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 19:09:14
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 19:09:14
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 19:08:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'This is the time captured in EMR.' (Site from System).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 21:45:25
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 21:45:10
User entered '00:00' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 21:45:10
User entered empty.	(b) (4), (b) (6) (b) (4)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 00:00'	System	24 Nov 2020 21:45:10
User entered empty.	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	24 Nov 2020 18:34:48
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 'per source the AE is on going' (Site from Safety).	Shannon Moyer (b) (4)	23 Nov 2020 07:44:44
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)	21 Oct 2020 13:18:53
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:25
Query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' canceled (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:20:29
User opened query 'PV Query: As the subject was hospitalized, please consider updating severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:20:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:44
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:43
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:41
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:03:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:03:12
User entered '08 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:54
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:55
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:57
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:50:58
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:51:00
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:51:07
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:40
User entered 'None (NONE)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:51
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:53
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:52:54
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:34:54
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'per source correct as is' (Site from Safety).	Shannon Moyer (b) (4)	23 Nov 2020 07:45:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:53:21
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:19:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 23:53:58
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:00:15
User entered 'DURING D22 SAFETY PHONE CALL ON 12-OCT-2020 MR. SUBJECT REPORTED A RECENT HOSPITALIZATION. HE REPORTS BEING DIAGNOSED WITH COLITIS ON 30-SEP-2020 AND WAS HOSPITALIZED FOR A TOTAL OF NINE DAYS. PATIENT WAS REPORTEDLY DISCHARGED FROM VALLEY REGIONAL MEDICAL CENTER ON 08-OCT-2020 AND WAS GIVEN A PRESCRIPTION FOR METRONIDAZOLE 500 MG TID AND LEVOFLOXACIN 500 MG ONCE A DAY. PATIENT STARTED BOTH OF THESE MEDICATIONS YESTERDAY ON 11-OCT-2020. PATIENT WAS SENT A MEDICAL RELEASE FORM VIA EMAIL IN ORDER TO OBTAIN RECORDS FROM HIS HOSPITALIZATION. WILL CONTINUE TO UPDATE INFORMATION AS IT BECOMES AVAILABLE.' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	21 Oct 2020 20:33:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:19:54
User opened query 'PV Query: Please provide the clinical course of illness.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:19:46
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:19:28

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'During D22 Safety Phone Call on 12-OCT-2020 Mr. (b) (6) reported a recent hospitalization. He reports being diagnosed with Colitis on 30-SEP-2020 and was hospitalized for a total of nine days. Patient was reportedly discharged from Valley Regional Medical Center on 08-OCT-2020 and was given a prescription for Metronidazole 500 mg TID and Levofloxacin 500 mg once a day. Patient started both of these medications yesterday on 11-OCT-2020. Patient was sent a medical release form via email in order to obtain records from his hospitalization. Will continue to update information as it becomes available.'	(b) (4), (b) (6)	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:52:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 19:08:24

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:01:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:30:02
User entered 'USA-US108-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	21 Oct 2020 20:29:58

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:01:26
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:22:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:22:32
Data point term sent to Coder	System	20 Oct 2020 22:21:22
User entered 'Pneumonia'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:03:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Was this a Solicited Adverse Reaction? = Yes. However, "PNEUMONIA" is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	23 Nov 2020 14:39:56
	(b) (4), (b) (6) (b) (4)	21 Nov 2020 00:04:04
Query 'Per CDM: Was this a Solicited Adverse Reaction? = Yes. However, "PNEUMONIA" is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:53:05
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	18 Nov 2020 09:52:47
User opened query 'Per CDM: Was this a Solicited Adverse Reaction? = Yes. However, "PNEUMONIA" is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6) (b) (4)	29 Oct 2020 09:56:06
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:09:10
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:09:13
User entered '30 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'this is the time in our emr.' (Site from System).	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 21:56:58
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Nov 2020 21:55:58
User entered '00:00' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Nov 2020 21:55:58
User entered empty.	(b) (4), (b) (6) (b) (4)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 00:00'	System	24 Nov 2020 21:55:58
User entered empty.	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:21
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:37
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:49
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:51
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		20 Oct 2020 22:21:59
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		20 Oct 2020 22:21:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Oct 2020 22:20:27
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:54
User entered '30 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:55
User entered '8 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:21:59
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:10:59
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:01
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:02
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 00:15:38
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:07
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:08
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:41
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:24:33
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:42
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:24:33
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:11:44
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:52:42
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:21:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 22:21:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:21:59
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 22:20:27
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:13:18
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 00:13:07
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 00:13:03
User opened query ' PV Query: Please provide the clinical course of illness.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:24
User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:53:06
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 22:24:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Oct 2020 22:24:33
User entered 'During D29 visit, patient reported he was diagnosed with pneumonia along with colitis and was admitted to the hospital. Colitis was already recorded on safety call however he did not report the pneumonia. Medical release record has been signed and updates will be provided once more information is available.' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 22:24:33
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 22:20:27
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 22:20:27

US3252516

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:52:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 22:21:59

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:52:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:25:06

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: PROPRANOLOL, PRODUCTSYNONYM: PROPANOLOL [PROPRANOLOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:27:56
Data point term sent to Coder	System	22 Sep 2020 05:26:30
User entered 'Propanolol'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 05:26:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 05:26:31
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 05:26:01
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 05:26:01

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 05:29:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 05:29:48
Data point term sent to Coder	System	22 Sep 2020 05:29:31
User entered 'Januvia'	Nancy Torrence (b) (4)	22 Sep 2020 05:28:33
	(b) (4)	

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Type II Diabetes Mellitus'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 05:28:33

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:41:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:41:25
Data point term sent to Coder	System	13 Oct 2020 03:05:00
Data point term sent to Coder	System	13 Oct 2020 03:04:00
User entered 'Metronidazole'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 03:04:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 03:04:11
User entered 'Colitis' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:04:11
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 03:03:47
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	05 Nov 2020 03:57:29
Query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication (COLITIS) is not listed in the solicited events as per protocol. Please review and update accordingly' answered with 'Solicited event indication updated.' (Site from DM).	Joanna Gurrola (b) (4)	03 Nov 2020 21:55:43
User opened query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication (COLITIS) is not listed in the solicited events as per protocol. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:29:16
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 03:03:47

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 05:39:25
Data point term sent to Coder	System	13 Oct 2020 03:06:01
User entered 'Levofloxacin'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Colitis'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

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

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:52:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 03:05:32

US3252516

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:52:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 05:34:27

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Oct/2020 10:00'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:52:19

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)	21 Oct 2020 20:13:49
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Oct/2020 20:14'	System	21 Oct 2020 20:14:03

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:52:19

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)	21 Oct 2020 20:30:26
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 20:14:03

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:52:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Oct/2020 20:30'	System	21 Oct 2020 20:30:52

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:52:19

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)	22 Oct 2020 14:19:24
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 20:30:52

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'USA-US108-2020-MRNA-1273-P301000004'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Yes (Y)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'No (N)'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Joel'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Solis'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered '5201 N. 10th Street'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'Mcallen'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'TX'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 14:00:42
User entered 'carmpa'	System	13 Oct 2020 14:00:26

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 20:13:49
User entered 'US'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:52:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Oct 2020 14:19:50
User entered '3'	System	21 Oct 2020 20:30:52
User entered '2'	System	21 Oct 2020 20:14:03
User entered '1'	System	13 Oct 2020 14:00:47

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:52:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '22/Oct/2020 14:19'	System	22 Oct 2020 14:19:50

US3252516

Folder: SAE USA-US108-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:52:19

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)	22 Oct 2020 14:20:58
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 14:19:50