

US3152426 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:09:36

All time stamps listed in this document are displayed in GMT

US3152426

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Participant ID

US3152426

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

US3152426

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	32
Age Units	YEARS
Age (Derived)	32
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Date of Informed Consent (<i>dd MMM yyyy</i>)	2 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" 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

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 04:13:57

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 04:13:57

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Condition	MIGRAINES
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)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	01 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 08:28
Height (xxx.x)	166 cm
Weight (xxx.x)	90.8 kg
BMI (xxx.x)	32.95108 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 04:13:56

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Date of assessment (dd MMM yyyy) 2 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	2 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 04:13:57

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 04:13:57

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

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

What was the participant's randomization number? 116074

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

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 08:28
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 09:57
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

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: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 04:13:57

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 OCT 2020

What was the treatment time? (00:00-23:59) 09:27 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 09:27

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	08:39 (24 HR)
Collection date and time (derived)	2 OCT 2020 08:39

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:55	2 OCT 2020 08:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

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: 11 Aug 2021 22:09:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

02 OCT 2020 09:58

PC Open Date & Time

02 OCT 2020 09:47

PC Close Date & Time

02 OCT 2020 12:17

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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 02 OCT 2020 13:12

PC Close Date & Time 03 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 20:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 13:34

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

07 OCT 2020 23:59

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 13:39

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

02 OCT 2020 09:59

PC Open Date & Time

02 OCT 2020 09:47

PC Close Date & Time

02 OCT 2020 12:17

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

02 OCT 2020 13:12

PC Close Date & Time

03 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 20:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 13:34

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

08 OCT 2020 00:00

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 13:40

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 09:59
PC Open Date & Time	02 OCT 2020 09:47
PC Close Date & Time	02 OCT 2020 12:17

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 13:12

PC Close Date & Time

03 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

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 ☐

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EAB) (1725)

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US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:05
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 13:35
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

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 ☒

PRODUCTION RELEASE (v12.003

56 of 2062

EAB) (1725)

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

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 ☒

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 13:40
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3152426

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	30 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	07:46 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 07:46
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 09:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3152426

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 30 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 30 OCT 2020

What was the treatment time? (00:00-23:59) 08:42 (24 HR)

Treatment Date and Time (derived) 30 OCT 2020 08:42

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3152426

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 OCT 2020

Collection time (00:00-23:59)

07:55 (24 HR)

Collection date and time (derived)

30 OCT 2020 07:55

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Collection date (dd MMM yyyy)			30 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:06	30 OCT 2020 08:06
Nasopharyngeal Swab 2	No		

US3152426

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

30 OCT 2020 09:16

PC Open Date & Time

30 OCT 2020 09:02

PC Close Date & Time

30 OCT 2020 11:32

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

30 OCT 2020 12:27

PC Close Date & Time

31 OCT 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

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

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 09:51

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 NOV 2020 09:09

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 NOV 2020 11:25

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

05 NOV 2020 00:09

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

06 NOV 2020 09:15

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 09:13

PC Open Date & Time

30 OCT 2020 09:02

PC Close Date & Time

30 OCT 2020 11:32

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

30 OCT 2020 12:27

PC Close Date & Time

31 OCT 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

02 NOV 2020 09:51

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

03 NOV 2020 09:09

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

04 NOV 2020 11:25

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

05 NOV 2020 00:10

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

06 NOV 2020 09:15

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 09:13
PC Open Date & Time	30 OCT 2020 09:02
PC Close Date & Time	30 OCT 2020 11:32

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

30 OCT 2020 12:27

PC Close Date & Time

31 OCT 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

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 ☐

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EAB) (1725)

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US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

Yes ☐

PC Time stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 09:52
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 09:09
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 11:26
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

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 ☒

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	05 NOV 2020 00:10
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

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 ☒

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EAB) (1725)

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

Yes <input type="checkbox"/>	
PC Time stamp	06 NOV 2020 09:15
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3152426

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:56

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 DEC 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

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 DEC 2020
Time of assessment (00:00-23:59)	08:07 (24 HR)
Vital Signs Date and Time (derived)	4 DEC 2020 08:07
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3152426

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

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.

US3152426

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 DEC 2020
Collection time (00:00-23:59)	08:11 (24 HR)
Collection date and time (derived)	4 DEC 2020 08:11

US3152426

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:13:57

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 12:07:23
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 12:01:28

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 15:43:32
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 13:05:42

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 17:20:57
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 15:47:53

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 07:10:09

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 07:37:45

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 10:30:17

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 08:45:58
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

Date and time of submission

14 FEB 2021 08:21:45

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 01:34:27

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 01:25:36

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

Date and time of submission

07 MAR 2021 06:15:22

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 21:46:45
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

Date and time of submission

21 MAR 2021 06:06:30

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 12:18:08

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 11:02:34

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 08:56:23
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 06:52:02

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 07:46:54

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 22:49:46

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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°F/38°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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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="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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3152426

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:09:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 01:26:03

US3152426

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:08:56

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:08:51

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3152426

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

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.

US3152426

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 APR 2021

Collection time (00:00-23:59)

07:47 (24 HR)

Collection date and time (derived)

14 APR 2021 07:47

US3152426

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3152426

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:09:36

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"/>

US3152426

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:09:36

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Date of updated informed consent (<i>dd MMM yyyy</i>)	8 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	8 JAN 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 08:15
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	8 JAN 2021
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 09:23
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

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.

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	8 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 JAN 2021

What was the treatment time? (00:00-23:59) 08:53 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 08:53

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

07:47 (24 HR)

Collection date and time (derived)

8 JAN 2021 07:47

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	07:52
Collection Date and Time (derived)	8 JAN 2021 07:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152426

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3152426

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

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)	9 APR 2021
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 13:18
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 APR 2021
Time of assessment (00:00-23:59)	14:38 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 14:38
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3152426

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

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.

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3152426

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 APR 2021

What was the treatment time? (00:00-23:59) 14:08 (24 HR)

Treatment Date and Time (derived) 9 APR 2021 14:08

Which arm was used to give treatment? Left Arm ☒
Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

SUBJECT RECEIVED DOSE 2
OUTSIDE OF WINDOW. SAFETY
CALL DAY 36 CONDUCTED
WITHIN WINDOW PER
PROTOCOL.

US3152426

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152426

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	5 MAR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:08 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 07:08
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3152426

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

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.

US3152426

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	5 MAR 2021
-------------------------------	------------

Collection time (00:00-23:59)	07:01 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	5 MAR 2021 07:01
------------------------------------	------------------

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Visit Date	10 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	True

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 17:43:28

Generated On: 11 Aug 2021 22:09:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	10 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3152426

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Mar 2021 02:15:40

Generated On: 11 Aug 2021 22:09:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Mar 2021 14:03:58

Generated On: 11 Aug 2021 22:09:36

AEID

Adverse event FATIGUE

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☒
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 03 OCT 2020

Start time (00:00-23:59) 09:00 (24 HR)

AE start date and time (derived) 03 OCT 2020 09:00

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 04 OCT 2020

End time (00:00-23:59) 09:00 (24 HR)

AE End Date and Time (derived) 04 OCT 2020 09:00

Severity Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Mar 2021 14:03:58

Generated On: 11 Aug 2021 22:09:36

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT FORGOT TO ENTER DAY 2 E-DIARY ENTRIES. ON SAFETY FOLLOW UP PHONE CALL, REPORTED FATIGUE ON DAY 2 THAT RESOLVED BY DAY 3.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Mar 2021 14:03:58

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Mar 2021 14:03:58

Generated On: 11 Aug 2021 22:09:36

AEID

Adverse event

BACK PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Mar 2021 14:03:58

Generated On: 11 Aug 2021 22:09:36

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☒
Dose Delayed ☐
Investigational Product ☐
Withdrawn ☐
Not Applicable ☐

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☒
Recovered/Resolved with Sequelae ☐
Recovering/Resolving ☐
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative SUBJECT REPORTED MILD
BACK SORENESS ON 7 DAY
SAFETY FOLLOW UP PHONE
CALL. DID NOT TAKE
MEDICATION. ATTRIBUTED TO
HOW SHE SLEPT BUT UNSURE.
RESOLVED ON 13 OCT 2020.
NEVER TOOK MEDICATION OR
SOUGHT MEDICAL ATTENTION.

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Mar 2021 14:03:58

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Mar 2021 14:03:58

Generated On: 11 Aug 2021 22:09:36

AEID

Adverse event

WORSENING
GASTROESOPHAGEAL REFLUX
DISEASE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Mar 2021 14:03:58

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Number of Days in ICU	
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 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 02:25:55

Generated On: 11 Aug 2021 22:09:36

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

Yes ☒

No ☐

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

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

	Intramuscular	<input type="checkbox"/>
	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 JAN 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"/>

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

	Intramuscular	<input type="checkbox"/>
	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 JAN 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"/>

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication FLAX SEED OIL

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☒
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

	Intramuscular	<input type="checkbox"/>
	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 1997	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING GERD

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

	Intramuscular	<input type="checkbox"/>
	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)	27 JAN 2021	
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"/>

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication MEGAFOOD BLOOD BUILDER
(VITAMIN C 15MG, FOLATE
600MCG, VITAMIN B12 30MCG,
IRON BISALICYLATE 20MG,
BEET ROOT 125MG)

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY ANEMIA

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	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)	27 JAN 2021	
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"/>

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50,000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 17 Apr 2021 21:12:12

Generated On: 11 Aug 2021 22:09:36

	Intramuscular	<input type="checkbox"/>
	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)	27 JAN 2021	
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"/>

US3152426

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 02:25:55

Generated On: 11 Aug 2021 22:09:36

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3152426

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:09:36

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

US3152426

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:09:36

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3152426 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

US3152426

Form: Participant Creation

Generated On: 11 Aug 2021 22:09:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:30:43
User entered 'US3152426'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 12:22:55

US3152426

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:59
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 13:32:36

US3152426

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:59
User entered '02 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 12:22:56

US3152426

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:59
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	02 Oct 2020 13:32:36

US3152426

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'SCRN'	System	02 Oct 2020 13:32:36

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 12:22:57

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '32'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'YEARS'	System	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '32'	System	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered 'Female (F)'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered 'I'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:09:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:25
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 13:33:02

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'Oct 2020'	System	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '2020'	System	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered 'Amendment 4 (4)' reason for change:	Devan Myers (b) (4)	02 Oct 2020 16:02:43
Data Entry Error	(b) (4)	
User entered 'Amendment 3 (3)'	Devan Myers (b) (4)	02 Oct 2020 13:33:15
	(b) (4)	

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 13:33:15

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 12:22:56

US3152426

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:09:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'I'	System	02 Oct 2020 13:33:20

US3152426

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:07:13
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 13:33:20

US3152426

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:09:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:11
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:38:27

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 19:40:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 19:40:52
Data point term sent to Coder	System	02 Oct 2020 19:39:53
User entered 'Vitamin D Deficiency'	Devan Myers (b) (4)	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered 'UN UNK 2020'	Devan Myers (b) (4)	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'Jan 2020'	System	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '2020'	System	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	02 Oct 2020 19:39:17

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 19:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 19:41:50
Data point term sent to Coder	System	02 Oct 2020 19:40:54
User entered 'Migraines'	Devan Myers (b) (4)	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered 'UN UNK 2010'	Devan Myers (b) (4)	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:08:59
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'Jan 2010'	System	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '2010'	System	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	02 Oct 2020 19:40:47

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 21:36:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 21:36:43
Data point term sent to Coder	System	10 Feb 2021 21:35:33
User entered 'gastroesophageal reflux disease'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered 'un UNK 2017'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'Jan 2017'	System	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '2017'	System	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	10 Feb 2021 21:34:45

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 21:36:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 21:36:44
Data point term sent to Coder	System	10 Feb 2021 21:35:32
User entered 'iron deficiency anemia'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '01 Sep 2020'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:03
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'Sep 2020'	System	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '2020'	System	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	10 Feb 2021 21:35:06

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered '08:28'	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '2 Oct 2020 08:28'	System	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered '166' cm	Devan Myers (b) (4)	02 Oct 2020 19:43:05
DataPoint set to visible.	(b) (4) System	02 Oct 2020 13:33:20

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered '90.8' kg	Devan Myers (b) (4)	02 Oct 2020 19:43:05
DataPoint set to visible.	(b) (4) System	02 Oct 2020 13:33:20

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered '32.95108'	System	02 Oct 2020 19:43:05
DataPoint set to visible.	System	02 Oct 2020 13:33:20

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'kg/m2'	System	02 Oct 2020 19:43:05
DataPoint set to visible.	System	02 Oct 2020 13:33:20

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'bpm'	System	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'breaths/min'	System	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'mmHg'	System	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:17
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered 'mmHg'	System	02 Oct 2020 19:43:05

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52

US3152426

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52

US3152426

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:50
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:43:43

US3152426

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:09:50
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:43:43

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:09:36

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:10:06
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:44:01

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered 'Urine (URINE)'	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered 'Negative (NEGATIVE)'	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User entered empty.	System	02 Oct 2020 19:44:15

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered 'I'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered '0'	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:09:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:22:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:11:29
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:45:29

US3152426

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:45:43

US3152426

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:18
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:45:43

US3152426

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:18
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	02 Oct 2020 19:45:43

US3152426

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'VISIT1'	System	02 Oct 2020 19:45:43

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered '02 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 13:02:36

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:50:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered '116074'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 13:02:36

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 13:02:36

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:05:50

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:05:50

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:05:50

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:05:50

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:05:50

US3152426

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:05:50
DataPoint set to visible.	System	02 Oct 2020 13:33:15

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User accepted default value 'Pre-Dose (PREDOSE)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '08:28'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '2 Oct 2020 08:28'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '37.0' C	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered 'Oral (Oral)'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '74'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'bpm'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '14'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'breaths/min'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '121'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '79'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered missing code ND - Not Done.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User accepted default value 'Post-Dose (POSTDOSE)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 19:49:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Oct 2020 19:49:46
User entered '09:57' reason for change: Data Entry Error	Devan Myers (b) (4)	02 Oct 2020 19:49:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 19:49:37
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:49:37
	(b) (4)	

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '2 Oct 2020 09:57'	System	02 Oct 2020 19:49:46
User entered empty.	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '37.0' C	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered 'Oral (Oral)'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '61'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'bpm'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '15'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'breaths/min'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '133'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:14:23
User entered '87'	Devan Myers (b) (4)	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	02 Oct 2020 19:49:37

US3152426

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 01:57:44
User closed query 'Per eCRF guidelines pg 18, Please record as No' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 01:57:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
Query 'Per eCRF guidelines pg 18, Please record as No' answered with 'Updated accordingly. ' (Site from CRA).	Azure Erskine (b) (4)	02 Dec 2020 18:46:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Dec 2020 18:45:43
User opened query 'Per eCRF guidelines pg 18, Please record as No' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:17:13
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:49:54

US3152426

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 01:57:44
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty; reason for change Data Entry Error	Azure Erskine (b) (4)	02 Dec 2020 18:45:43
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:49:54

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User closed query 'Per eCRF guidelines pg 18, please record as No' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 14:15:33
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
Query 'Per eCRF guidelines pg 18, please record as No' answered with 'updated accordingly' (Site from CRA).	Devan Myers (b) (4)	02 Dec 2020 14:49:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Dec 2020 14:49:43
User opened query 'Per eCRF guidelines pg 18, please record as No' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:20:32
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty; reason for change Data Entry Error	Devan Myers (b) (4)	02 Dec 2020 14:49:43
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:03
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:50:07
	(b) (4)	

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty; reason for change Data Entry Error	Devan Myers (b) (4)	02 Dec 2020 14:49:43
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:05
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User entered 'Urine (URINE)'	Devan Myers (b) (4)	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty; reason for change Data Entry Error	Devan Myers (b) (4)	02 Dec 2020 14:49:43
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 19:50:11
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Devan Myers (b) (4)	02 Oct 2020 19:50:11
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 19:50:07
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
User entered empty; reason for change Data Entry Error	Devan Myers (b) (4)	02 Dec 2020 14:49:43
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 14:15:47
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:20:12
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:19:42
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered empty.	System	02 Oct 2020 19:50:07

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered '09:27'	Devan Myers (b) (4)	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered '2 Oct 2020 09:27'	System	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:06
User entered 'ONCE'	System	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 13:35:35

US3152426

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:50:28

US3152426

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:33
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:50:28

US3152426

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:33
User entered '08:39'	Devan Myers (b) (4)	02 Oct 2020 19:50:28

US3152426

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered '2 Oct 2020 08:39'	System	02 Oct 2020 19:50:28

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:56
User entered '2 Oct 2020'	Devan Myers (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:56
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:56
User entered '08:55'	Devan Myers (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered '2 Oct 2020 08:55'	System	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:56
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:22:56
User entered empty.	Devan Myers (b) (4)	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered empty.	System	02 Oct 2020 19:50:49

US3152426

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:23:13
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:50:55

US3152426

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	02 Oct 2020 19:50:55

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:24', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '73d9153b-7459-46b1-9df8-fd38bddbea2b' User entered 'Yes (Y)'	System	02 Oct 2020 13:58:42
	System	02 Oct 2020 13:58:42

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '73d9153b-7459-46b1-9df8-fd38bddbea2b' User entered '98.6'	System	02 Oct 2020 13:58:42
	System	02 Oct 2020 13:58:42

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:33', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '73d9153b-7459-46b1-9df8-fd38bddbea2b' User entered 'No (N)'	System	02 Oct 2020 13:58:42
	System	02 Oct 2020 13:58:42

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '73d9153b-7459-46b1-9df8-fd38bddbea2b' User entered '02 Oct 2020 09:58'	System	02 Oct 2020 13:58:42
	System	02 Oct 2020 13:58:42

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 09:47'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 12:17'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 13:12'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 2'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 3'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:01', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '38261226-47c0-4830-a09c-913bf65ef3f7' User entered 'Yes (Y)'	System	05 Oct 2020 00:04:24
	System	05 Oct 2020 00:04:24

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:13', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '38261226-47c0-4830-a09c-913bf65ef3f7' User entered '97.6'	System	05 Oct 2020 00:04:24
	System	05 Oct 2020 00:04:24

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:18', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '38261226-47c0-4830-a09c-913bf65ef3f7'	System	05 Oct 2020 00:04:24
User entered 'No (N)'	System	05 Oct 2020 00:04:24

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:22', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '38261226-47c0-4830-a09c-913bf65ef3f7' User entered '04 Oct 2020 20:04'	System	05 Oct 2020 00:04:24
	System	05 Oct 2020 00:04:24

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 4'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 5'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:33:19', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '98182035-66e1-47f5-98a7-c6d88d9da44f' User entered 'Yes (Y)'	System	06 Oct 2020 17:34:23
	System	06 Oct 2020 17:34:23

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:10', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '98182035-66e1-47f5-98a7-c6d88d9da44f' User entered '96.2'	System	06 Oct 2020 17:34:23
	System	06 Oct 2020 17:34:23

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:14', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '98182035-66e1-47f5-98a7-c6d88d9da44f' User entered 'No (N)'	System	06 Oct 2020 17:34:23
	System	06 Oct 2020 17:34:23

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:19', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '98182035-66e1-47f5-98a7-c6d88d9da44f' User entered '06 Oct 2020 13:34'	System	06 Oct 2020 17:34:23
	System	06 Oct 2020 17:34:23

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 6'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-07T23:59:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '4692af90-e117-4666-9450-12f6b4d33db7' User entered 'Yes (Y)'	System	08 Oct 2020 03:59:50
	System	08 Oct 2020 03:59:50

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-07T23:59:39', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '4692af90-e117-4666-9450-12f6b4d33db7' User entered '97.6'	System	08 Oct 2020 03:59:50
	System	08 Oct 2020 03:59:50

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-07T23:59:43', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '4692af90-e117-4666-9450-12f6b4d33db7'	System	08 Oct 2020 03:59:50
User entered 'No (N)'	System	08 Oct 2020 03:59:50

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-07T23:59:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '4692af90-e117-4666-9450-12f6b4d33db7' User entered '07 Oct 2020 23:59'	System	08 Oct 2020 03:59:50
	System	08 Oct 2020 03:59:50

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 7'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:39:27', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'fdc341ad-0d5a-44f1-8011-401804302561' User entered 'Yes (Y)'	System	08 Oct 2020 17:40:02
	System	08 Oct 2020 17:40:02

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:39:35', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'fdc341ad-0d5a-44f1-8011-401804302561' User entered '98.0'	System	08 Oct 2020 17:40:02
	System	08 Oct 2020 17:40:02

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:39:56', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'fdc341ad-0d5a-44f1-8011-401804302561'	System	08 Oct 2020 17:40:02
User entered 'No (N)'	System	08 Oct 2020 17:40:02

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:39:59', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'fdc341ad-0d5a-44f1-8011-401804302561' User entered '08 Oct 2020 13:39'	System	08 Oct 2020 17:40:02
	System	08 Oct 2020 17:40:02

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:51', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e56c1a35-81e5-4c06-bfaa-260135ab8343' User entered 'None (1)'	System	02 Oct 2020 13:59:06
	System	02 Oct 2020 13:59:06

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:55', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e56c1a35-81e5-4c06-bfaa-260135ab8343' User entered 'No (N)'	System	02 Oct 2020 13:59:06
	System	02 Oct 2020 13:59:06

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:58:58', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e56c1a35-81e5-4c06-bfaa-260135ab8343' User entered 'No (N)'	System	02 Oct 2020 13:59:06
	System	02 Oct 2020 13:59:06

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:01', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e56c1a35-81e5-4c06-bfaa-260135ab8343'	System	02 Oct 2020 13:59:06
User entered 'None (1)'	System	02 Oct 2020 13:59:06

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:04', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e56c1a35-81e5-4c06-bfaa-260135ab8343' User entered '02 Oct 2020 09:59'	System	02 Oct 2020 13:59:06
	System	02 Oct 2020 13:59:06

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 09:47'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 12:17'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 13:12'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 2'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 3'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '8b8b852f-d4e6-42f3-861f-4b948dd8d6b5'	System	05 Oct 2020 00:04:49
User entered 'None (1)'	System	05 Oct 2020 00:04:49

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:35', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '8b8b852f-d4e6-42f3-861f-4b948dd8d6b5'	System	05 Oct 2020 00:04:49
User entered 'No (N)'	System	05 Oct 2020 00:04:49

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:40', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '8b8b852f-d4e6-42f3-861f-4b948dd8d6b5' User entered 'No (N)'	System	05 Oct 2020 00:04:49
	System	05 Oct 2020 00:04:49

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:45', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '8b8b852f-d4e6-42f3-861f-4b948dd8d6b5'	System	05 Oct 2020 00:04:49
User entered 'None (1)'	System	05 Oct 2020 00:04:49

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:04:48', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '8b8b852f-d4e6-42f3-861f-4b948dd8d6b5'	System	05 Oct 2020 00:04:49
User entered '04 Oct 2020 20:04'	System	05 Oct 2020 00:04:49

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 4'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 5'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:24', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'c39b7480-aa8e-426b-a61b-141e57eef0d0'	System	06 Oct 2020 17:34:38
User entered 'None (1)'	System	06 Oct 2020 17:34:38

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:27', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'c39b7480-aa8e-426b-a61b-141e57eef0d0' User entered 'No (N)'	System	06 Oct 2020 17:34:38
	System	06 Oct 2020 17:34:38

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'c39b7480-aa8e-426b-a61b-141e57eef0d0'	System	06 Oct 2020 17:34:38
User entered 'No (N)'	System	06 Oct 2020 17:34:38

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:31', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'c39b7480-aa8e-426b-a61b-141e57eef0d0'	System	06 Oct 2020 17:34:38
User entered 'None (1)'	System	06 Oct 2020 17:34:38

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'c39b7480-aa8e-426b-a61b-141e57eef0d0' User entered '06 Oct 2020 13:34'	System	06 Oct 2020 17:34:38
	System	06 Oct 2020 17:34:38

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 6'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-07T23:59:54', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5126a5ec-d643-4819-a97a-68b3beaeaa86'	System	08 Oct 2020 04:00:30
User entered 'None (1)'	System	08 Oct 2020 04:00:30

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-07T23:59:57', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5126a5ec-d643-4819-a97a-68b3beaeaa86' User entered 'No (N)'	System	08 Oct 2020 04:00:30
	System	08 Oct 2020 04:00:30

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:01', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5126a5ec-d643-4819-a97a-68b3beaeaa86'	System	08 Oct 2020 04:00:30
User entered 'No (N)'	System	08 Oct 2020 04:00:30

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:11', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5126a5ec-d643-4819-a97a-68b3beaeaa86'	System	08 Oct 2020 04:00:30
User entered 'None (1)'	System	08 Oct 2020 04:00:30

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:26', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5126a5ec-d643-4819-a97a-68b3beaeaa86' User entered '08 Oct 2020 00:00'	System	08 Oct 2020 04:00:30
	System	08 Oct 2020 04:00:30

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 7'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:02', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'eafcb41-ddb8-494c-b8e8-2afe4620e1ea'	System	08 Oct 2020 17:40:11
User entered 'None (1)'	System	08 Oct 2020 17:40:11

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:04', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'eafcbe41-ddb8-494c-b8e8-2afe4620e1ea' User entered 'No (N)'	System	08 Oct 2020 17:40:11
	System	08 Oct 2020 17:40:11

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:05', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'eafcbe41-ddb8-494c-b8e8-2afe4620e1ea' User entered 'No (N)'	System	08 Oct 2020 17:40:11
	System	08 Oct 2020 17:40:11

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:07', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'eafcbe41-ddb8-494c-b8e8-2afe4620e1ea' User entered 'None (1)'	System	08 Oct 2020 17:40:11
	System	08 Oct 2020 17:40:11

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:09', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'eafcbe41-ddb8-494c-b8e8-2afe4620e1ea' User entered '08 Oct 2020 13:40'	System	08 Oct 2020 17:40:11
	System	08 Oct 2020 17:40:11

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:09', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddeb4ab' User entered 'None (0)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:14', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddebf4ab' User entered 'None (0)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:16', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddeb4ab' User entered 'None (0)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:18', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddeb4ab' User entered 'None (0)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:21', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddeb4ab' User entered 'None (0)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddebf4ab' User entered 'None (0)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:44', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddeb4ab' User entered 'No (N)'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-02T09:59:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ac254bf3-6063-42e9-9a12-39b0ddeb4ab' User entered '02 Oct 2020 09:59'	System	02 Oct 2020 13:59:51
	System	02 Oct 2020 13:59:51

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 09:47'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 12:17'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Oct 2020 13:12'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 2'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 3'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:07', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'None (0)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'None (0)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:27', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'None (0)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:31', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'None (0)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'None (0)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'None (0)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:50', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered 'No (N)'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-04T20:05:54', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7566c91f-1dc2-4bfd-8621-f8ec123bc51a' User entered '04 Oct 2020 20:05'	System	05 Oct 2020 00:05:55
	System	05 Oct 2020 00:05:55

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 4'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 5'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:39', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'None (0)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:51', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'None (0)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:53', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'None (0)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:55', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'None (0)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:57', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'None (0)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:34:58', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'None (0)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:35:02', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered 'No (N)'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-06T13:35:04', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '81c0396f-6fad-43b4-a352-44d51f9ba318' User entered '06 Oct 2020 13:35'	System	06 Oct 2020 17:35:10
	System	06 Oct 2020 17:35:10

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 6'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:31', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'None (0)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:33', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'None (0)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:35', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'None (0)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'None (0)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:39', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'None (0)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:41', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'None (0)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:47', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered 'No (N)'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T00:00:55', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '6872f73c-2c65-4259-b963-133bf93238d9' User entered '08 Oct 2020 00:00'	System	08 Oct 2020 04:00:59
	System	08 Oct 2020 04:00:59

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	02 Oct 2020 13:35:35
User entered 'Day 7'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:12', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'None (0)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:13', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'None (0)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:14', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'None (0)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:15', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'None (0)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:17', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'None (0)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:18', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'None (0)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:21', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered 'No (N)'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-08T13:40:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ff9a832f-b540-4c58-9050-6cae40e89b89' User entered '08 Oct 2020 13:40'	System	08 Oct 2020 17:40:27
	System	08 Oct 2020 17:40:27

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 13:35:35

US3152426

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 13:35:35

US3152426

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:23:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:06:59

US3152426

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:23:44
User entered '09 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:06:59

US3152426

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:23:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 16:06:59

US3152426

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:23:44
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 16:06:59

US3152426

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:24:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:07:03

US3152426

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	09 Oct 2020 16:07:03

US3152426

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:05:24

US3152426

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:22
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:05:24

US3152426

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 18:05:24

US3152426

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:26:22
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:05:24

US3152426

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:05:29

US3152426

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	16 Oct 2020 18:05:29

US3152426

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:09
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	27 Oct 2020 14:24:31
	(b) (4)	

US3152426

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:09
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Nov 2020 13:59:22
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'tried contact within window ' (Site from System).	Jemario Blackwell (b) (4)	27 Oct 2020 14:24:55
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Oct 2020 14:24:31
User entered '27 Oct 2020'	Jemario Blackwell (b) (4)	27 Oct 2020 14:24:31

US3152426

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:09
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4) (b) (4)	27 Oct 2020 14:24:31

US3152426

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:30:09
User entered empty.	Jemario Blackwell (b) (4)	27 Oct 2020 14:24:31

US3152426

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:11
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	27 Oct 2020 14:25:02

US3152426

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	27 Oct 2020 14:25:02

US3152426

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:47
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:07:06
	(b) (4)	

US3152426

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:47
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:07:06
	(b) (4)	

US3152426

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:31:47
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	30 Oct 2020 13:07:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'VISIT2'	System	30 Oct 2020 13:07:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User accepted default value 'Pre-Dose (PREDOSE)'	Devan Myers (b) (4) (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '07:46'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '30 Oct 2020 07:46'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '37.1' C	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered 'Oral (Oral)'	Devan Myers (b) (4)	30 Oct 2020 13:19:41
	(b) (4)	

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '79'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'bpm'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '15'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'breaths/min'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '114'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '82'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User accepted default value 'Post-Dose (POSTDOSE)'	Devan Myers (b) (4) (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '09:12'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '30 Oct 2020 09:12'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '36.9' C	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered 'Oral (Oral)'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '65'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'bpm'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '14'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'breaths/min'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '109'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:32
User entered '80'	Devan Myers (b) (4)	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	30 Oct 2020 13:19:41

US3152426

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:52
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:07:15

US3152426

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:33:52
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:07:15

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered 'Urine (URINE)'	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered 'Negative (NEGATIVE)'	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered 'No (N)'	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:22
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered empty.	System	30 Oct 2020 13:07:36

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'MRNA-1273 OR PLACEBO'	System	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered '08:42'	Devan Myers (b) (4)	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '30 Oct 2020 08:42'	System	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:34
User entered 'ONCE'	System	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'INTRAMUSCULAR'	System	30 Oct 2020 12:57:06

US3152426

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:11
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:08:01

US3152426

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:11
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:08:01

US3152426

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:11
User entered '07:55'	Devan Myers (b) (4)	30 Oct 2020 13:08:01

US3152426

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '30 Oct 2020 07:55'	System	30 Oct 2020 13:08:01

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:34
User entered '30 Oct 2020'	Devan Myers (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Devan Myers (b) (4) (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:34
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:34
User entered '08:06'	Devan Myers (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '30 Oct 2020 08:06'	System	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Devan Myers (b) (4) (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:34
User entered 'No (N)'	Devan Myers (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:34
User entered empty.	Devan Myers (b) (4)	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered empty.	System	30 Oct 2020 13:08:42

US3152426

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:35:47
User entered 'Yes (Y)'	Devan Myers (b) (4)	30 Oct 2020 13:10:03

US3152426

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '1'	System	30 Oct 2020 13:10:03

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:15:32', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '3ffbfaed-211b-4010-8965-3ef9a49aab77'	System	30 Oct 2020 13:16:49
User entered 'Yes (Y)'	System	30 Oct 2020 13:16:49

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:16:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '3ffbfaed-211b-4010-8965-3ef9a49aab77'	System	30 Oct 2020 13:16:49
User entered '98.5'	System	30 Oct 2020 13:16:49

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:16:38', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '3ffbfaed-211b-4010-8965-3ef9a49aab77'	System	30 Oct 2020 13:16:49
User entered 'No (N)'	System	30 Oct 2020 13:16:49

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:16:44', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '3ffbfaed-211b-4010-8965-3ef9a49aab77'	System	30 Oct 2020 13:16:49
User entered '30 Oct 2020 09:16'	System	30 Oct 2020 13:16:49

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 09:02'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 11:32'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 12:27'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 2'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 3'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:05', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '867b70b3-dddf-4cfb-a0ee-021d38b84ffa' User entered 'Yes (Y)'	System	02 Nov 2020 14:51:22
	System	02 Nov 2020 14:51:22

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:13', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '867b70b3-dddf-4cfb-a0ee-021d38b84ffa' User entered '97.2'	System	02 Nov 2020 14:51:22
	System	02 Nov 2020 14:51:22

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:16', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '867b70b3-dddf-4cfb-a0ee-021d38b84ffa' User entered 'No (N)'	System	02 Nov 2020 14:51:22
	System	02 Nov 2020 14:51:22

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:19', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '867b70b3-dddf-4cfb-a0ee-021d38b84ffa' User entered '02 Nov 2020 09:51'	System	02 Nov 2020 14:51:22
	System	02 Nov 2020 14:51:22

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 4'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:15', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0409850c-6cf1-48cc-b35c-3128531877b0' User entered 'Yes (Y)'	System	03 Nov 2020 14:09:29
	System	03 Nov 2020 14:09:29

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:20', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0409850c-6cf1-48cc-b35c-3128531877b0' User entered '97.6'	System	03 Nov 2020 14:09:29
	System	03 Nov 2020 14:09:29

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:24', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0409850c-6cf1-48cc-b35c-3128531877b0' User entered 'No (N)'	System	03 Nov 2020 14:09:29
	System	03 Nov 2020 14:09:29

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:26', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0409850c-6cf1-48cc-b35c-3128531877b0' User entered '03 Nov 2020 09:09'	System	03 Nov 2020 14:09:29
	System	03 Nov 2020 14:09:29

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 5'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '343bb722-ea10-4b32-9dff-fbe110c31645'	System	04 Nov 2020 16:25:50
User entered 'Yes (Y)'	System	04 Nov 2020 16:25:50

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:42', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '343bb722-ea10-4b32-9dff-fbe110c31645' User entered '97.2'	System	04 Nov 2020 16:25:50
	System	04 Nov 2020 16:25:50

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:44', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '343bb722-ea10-4b32-9dff-fbe110c31645'	System	04 Nov 2020 16:25:50
User entered 'No (N)'	System	04 Nov 2020 16:25:50

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '343bb722-ea10-4b32-9dff-fbe110c31645' User entered '04 Nov 2020 11:25'	System	04 Nov 2020 16:25:50
	System	04 Nov 2020 16:25:50

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 6'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:09:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e6f41e20-0f6e-4ccc-be32-f85cc7e81d29'	System	05 Nov 2020 05:09:58
User entered 'Yes (Y)'	System	05 Nov 2020 05:09:58

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:09:44', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e6f41e20-0f6e-4ccc-be32-f85cc7e81d29' User entered '97.6'	System	05 Nov 2020 05:09:58
	System	05 Nov 2020 05:09:58

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:09:47', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e6f41e20-0f6e-4ccc-be32-f85cc7e81d29'	System	05 Nov 2020 05:09:58
User entered 'No (N)'	System	05 Nov 2020 05:09:58

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:09:52', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e6f41e20-0f6e-4ccc-be32-f85cc7e81d29'	System	05 Nov 2020 05:09:58
User entered '05 Nov 2020 00:09'	System	05 Nov 2020 05:09:58

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 7'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:21', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd7d8438d-836c-41ea-a693-0c2b05b29c67'	System	06 Nov 2020 14:15:36
User entered 'Yes (Y)'	System	06 Nov 2020 14:15:36

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:26', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd7d8438d-836c-41ea-a693-0c2b05b29c67' User entered '97.1'	System	06 Nov 2020 14:15:36
	System	06 Nov 2020 14:15:36

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd7d8438d-836c-41ea-a693-0c2b05b29c67'	System	06 Nov 2020 14:15:36
User entered 'No (N)'	System	06 Nov 2020 14:15:36

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:32', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd7d8438d-836c-41ea-a693-0c2b05b29c67' User entered '06 Nov 2020 09:15'	System	06 Nov 2020 14:15:36
	System	06 Nov 2020 14:15:36

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:00', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd75f71f0-bda0-41e0-af62-25eeeab2f441'	System	30 Oct 2020 13:13:24
User entered 'None (1)'	System	30 Oct 2020 13:13:24

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:03', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd75f71f0-bda0-41e0-af62-25eeeab2f441' User entered 'No (N)'	System	30 Oct 2020 13:13:24
	System	30 Oct 2020 13:13:24

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:05', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd75f71f0-bda0-41e0-af62-25eeeab2f441' User entered 'No (N)'	System	30 Oct 2020 13:13:24
	System	30 Oct 2020 13:13:24

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:19', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd75f71f0-bda0-41e0-af62-25eeeab2f441'	System	30 Oct 2020 13:13:24
User entered 'None (1)'	System	30 Oct 2020 13:13:24

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:22', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd75f71f0-bda0-41e0-af62-25eeeab2f441'	System	30 Oct 2020 13:13:24
User entered '30 Oct 2020 09:13'	System	30 Oct 2020 13:13:24

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 09:02'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 11:32'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 12:27'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 2'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 3'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '9e17eef9-2dc6-4c7a-82c1-d09ebdd309e4' User entered 'None (1)'	System	02 Nov 2020 14:51:37
	System	02 Nov 2020 14:51:37

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:26', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '9e17eef9-2dc6-4c7a-82c1-d09ebdd309e4' User entered 'No (N)'	System	02 Nov 2020 14:51:37
	System	02 Nov 2020 14:51:37

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '9e17eef9-2dc6-4c7a-82c1-d09ebdd309e4' User entered 'No (N)'	System	02 Nov 2020 14:51:37
	System	02 Nov 2020 14:51:37

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:31', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '9e17eef9-2dc6-4c7a-82c1-d09ebdd309e4' User entered 'None (1)'	System	02 Nov 2020 14:51:37
	System	02 Nov 2020 14:51:37

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:51:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '9e17eef9-2dc6-4c7a-82c1-d09ebdd309e4' User entered '02 Nov 2020 09:51'	System	02 Nov 2020 14:51:37
	System	02 Nov 2020 14:51:37

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 4'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'bce4a5f7-c601-41c5-b3cc-3950b04ad907'	System	03 Nov 2020 14:09:41
User entered 'None (1)'	System	03 Nov 2020 14:09:41

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:31', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'bce4a5f7-c601-41c5-b3cc-3950b04ad907'	System	03 Nov 2020 14:09:41
User entered 'No (N)'	System	03 Nov 2020 14:09:41

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:33', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'bce4a5f7-c601-41c5-b3cc-3950b04ad907'	System	03 Nov 2020 14:09:41
User entered 'No (N)'	System	03 Nov 2020 14:09:41

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:35', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'bce4a5f7-c601-41c5-b3cc-3950b04ad907'	System	03 Nov 2020 14:09:41
User entered 'None (1)'	System	03 Nov 2020 14:09:41

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'bce4a5f7-c601-41c5-b3cc-3950b04ad907' User entered '03 Nov 2020 09:09'	System	03 Nov 2020 14:09:41
	System	03 Nov 2020 14:09:41

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 5'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:49', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b85a6da4-74db-46cd-9026-ffac45d2a6cb' User entered 'None (1)'	System	04 Nov 2020 16:26:03
	System	04 Nov 2020 16:26:03

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:50', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b85a6da4-74db-46cd-9026-ffac45d2a6cb' User entered 'No (N)'	System	04 Nov 2020 16:26:03
	System	04 Nov 2020 16:26:03

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:52', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b85a6da4-74db-46cd-9026-ffac45d2a6cb' User entered 'No (N)'	System	04 Nov 2020 16:26:03
	System	04 Nov 2020 16:26:03

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:54', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b85a6da4-74db-46cd-9026-ffac45d2a6cb' User entered 'None (1)'	System	04 Nov 2020 16:26:03
	System	04 Nov 2020 16:26:03

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:25:56', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b85a6da4-74db-46cd-9026-ffac45d2a6cb' User entered '04 Nov 2020 11:25'	System	04 Nov 2020 16:26:03
	System	04 Nov 2020 16:26:03

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 6'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:09:57', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'da1dc1d9-b1b5-401f-a5ee-355c2adc94ea' User entered 'None (1)'	System	05 Nov 2020 05:10:12
	System	05 Nov 2020 05:10:12

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:01', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'da1dc1d9-b1b5-401f-a5ee-355c2adc94ea' User entered 'No (N)'	System	05 Nov 2020 05:10:12
	System	05 Nov 2020 05:10:12

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:04', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'da1dc1d9-b1b5-401f-a5ee-355c2adc94ea' User entered 'No (N)'	System	05 Nov 2020 05:10:12
	System	05 Nov 2020 05:10:12

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:06', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'da1dc1d9-b1b5-401f-a5ee-355c2adc94ea' User entered 'None (1)'	System	05 Nov 2020 05:10:12
	System	05 Nov 2020 05:10:12

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:10', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'da1dc1d9-b1b5-401f-a5ee-355c2adc94ea' User entered '05 Nov 2020 00:10'	System	05 Nov 2020 05:10:12
	System	05 Nov 2020 05:10:12

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 7'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd34a47be-98e5-4e87-81c4-dd18e46e9af1' User entered 'None (1)'	System	06 Nov 2020 14:15:43
	System	06 Nov 2020 14:15:43

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:36', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd34a47be-98e5-4e87-81c4-dd18e46e9af1' User entered 'No (N)'	System	06 Nov 2020 14:15:43
	System	06 Nov 2020 14:15:43

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:38', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd34a47be-98e5-4e87-81c4-dd18e46e9af1' User entered 'No (N)'	System	06 Nov 2020 14:15:43
	System	06 Nov 2020 14:15:43

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:39', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd34a47be-98e5-4e87-81c4-dd18e46e9af1' User entered 'None (1)'	System	06 Nov 2020 14:15:43
	System	06 Nov 2020 14:15:43

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:41', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'd34a47be-98e5-4e87-81c4-dd18e46e9af1' User entered '06 Nov 2020 09:15'	System	06 Nov 2020 14:15:43
	System	06 Nov 2020 14:15:43

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:27', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'None (0)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:31', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'None (0)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:33', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'None (0)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'None (0)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:36', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'None (0)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:38', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'None (0)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:42', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered 'No (N)'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-10-30T09:13:52', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '529e75e3-5746-4842-bfad-f792263a8b73' User entered '30 Oct 2020 09:13'	System	30 Oct 2020 13:13:56
	System	30 Oct 2020 13:13:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 09:02'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 11:32'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '30 Oct 2020 12:27'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 2'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 3'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:03', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'None (0)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:07', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'None (0)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:11', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'None (0)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:13', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'None (0)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:15', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'None (0)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:17', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'None (0)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:20', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered 'No (N)'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-02T09:52:22', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '113af18d-9d1c-4021-a974-db7da63d0298' User entered '02 Nov 2020 09:52'	System	02 Nov 2020 14:52:27
	System	02 Nov 2020 14:52:27

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 4'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:40', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'None (0)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:41', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'None (0)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:42', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'None (0)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:44', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'None (0)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:45', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'None (0)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:47', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'None (0)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:50', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered 'No (N)'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-03T09:09:52', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1e3edf50-4c76-408b-a58c-4db3e942ae4f' User entered '03 Nov 2020 09:09'	System	03 Nov 2020 14:09:56
	System	03 Nov 2020 14:09:56

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 5'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:00', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'None (0)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:02', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'None (0)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:03', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'None (0)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:04', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'None (0)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:06', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'None (0)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:07', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'None (0)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:09', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered 'No (N)'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-04T11:26:11', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'ed6cbc09-ed1d-434f-a9d1-379efa042e61' User entered '04 Nov 2020 11:26'	System	04 Nov 2020 16:26:17
	System	04 Nov 2020 16:26:17

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 6'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:14', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'None (0)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:16', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'None (0)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:18', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'None (0)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:21', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'None (0)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'None (0)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:25', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'None (0)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered 'No (N)'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-05T00:10:33', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '18cc43eb-3a89-4aad-a0f8-9b21214275fd' User entered '05 Nov 2020 00:10'	System	05 Nov 2020 05:10:34
	System	05 Nov 2020 05:10:34

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
Data entry locked.	System	30 Oct 2020 12:57:06
User entered 'Day 7'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:43', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'None (0)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:45', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'None (0)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'None (0)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:47', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'None (0)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:48', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'None (0)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:49', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'None (0)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:54', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered 'No (N)'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7128C82D-D4C3-428C-BC11-B49C7B85F8EA)', Time: '2020-11-06T09:15:55', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '967ebe1b-7082-418c-ba98-ab698e8cb120' User entered '06 Nov 2020 09:15'	System	06 Nov 2020 14:15:59
	System	06 Nov 2020 14:15:59

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 12:57:06

US3152426

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:09:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:56:01
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 12:57:06

US3152426

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:36:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 19:02:45

US3152426

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:36:30
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 19:02:45

US3152426

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:36:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 19:02:45

US3152426

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:36:30
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 19:02:45

US3152426

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:36:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 19:02:59

US3152426

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	06 Nov 2020 19:02:59

US3152426

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:37:45
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	16 Nov 2020 21:46:44
	(b) (4)	

US3152426

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:37:45
User entered '16 Nov 2020'	Jemario Blackwell (b) (4) (b) (4)	16 Nov 2020 21:46:44

US3152426

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:37:45
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4) (b) (4)	16 Nov 2020 21:46:44

US3152426

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:37:45
User entered empty.	Jemario Blackwell (b) (4)	16 Nov 2020 21:46:44

US3152426

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:38:23
User entered 'Yes (Y)'	Jemario Blackwell (b) (4) (b) (4)	16 Nov 2020 21:46:48

US3152426

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	16 Nov 2020 21:46:48

US3152426

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:32:23
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	20 Nov 2020 17:59:47
	(b) (4)	

US3152426

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:32:23
User entered '20 Nov 2020'	Jemario Blackwell (b) (4)	20 Nov 2020 17:59:47
	(b) (4)	

US3152426

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:32:23
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4) (b) (4)	20 Nov 2020 17:59:47

US3152426

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:32:23
User entered empty.	Jemario Blackwell (b) (4)	20 Nov 2020 17:59:47

US3152426

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:32:31
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	20 Nov 2020 17:59:50
	(b) (4)	

US3152426

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	20 Nov 2020 17:59:50

US3152426

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:33:32
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	04 Dec 2020 13:48:36

US3152426

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:33:32
User entered '4 Dec 2020'	Tanya Alexander (b) (4)	04 Dec 2020 13:48:36

US3152426

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:33:32
User entered 'Clinic (Clinic)'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:48:36

US3152426

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'VISIT3'	System	04 Dec 2020 13:48:36

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '4 Dec 2020'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '08:07'	Tanya Alexander (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '4 Dec 2020 08:07'	System	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '37.1' C	Tanya Alexander (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered 'Oral (Oral)'	Tanya Alexander (b) (4)	04 Dec 2020 13:49:37
	(b) (4)	

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered empty.	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '69'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'bpm'	System	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '15'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'breaths/min'	System	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '120'	Tanya Alexander (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:07
User entered '88'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered 'mmHg'	System	04 Dec 2020 13:49:37

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43

US3152426

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43

US3152426

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:27
User entered 'No (N)'	Tanya Alexander (b) (4)	04 Dec 2020 13:49:43

US3152426

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:27
User entered empty.	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:49:43

US3152426

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:49
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	04 Dec 2020 13:51:52

US3152426

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:49
User entered '4 Dec 2020'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:51:52

US3152426

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:49
User entered '08:11'	Tanya Alexander (b) (4) (b) (4)	04 Dec 2020 13:51:52

US3152426

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '4 Dec 2020 08:11'	System	04 Dec 2020 13:51:52

US3152426

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:13:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:34:59
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	04 Dec 2020 13:51:57
	(b) (4)	

US3152426

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:43
User entered '1'	System	04 Dec 2020 13:51:57

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-08T12:07:17', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '99a06980-d22c-4490-a9be-d4c5107ae5d6'	System	08 Dec 2020 17:07:25
User entered 'No (N)'	System	08 Dec 2020 17:07:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-08T12:07:20', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '99a06980-d22c-4490-a9be-d4c5107ae5d6' User entered 'No (N)'	System	08 Dec 2020 17:07:25
	System	08 Dec 2020 17:07:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-08T12:07:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '99a06980-d22c-4490-a9be-d4c5107ae5d6' User entered '08 Dec 2020 12:07:23'	System	08 Dec 2020 17:07:25
	System	08 Dec 2020 17:07:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-15T12:01:20', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5cd6d97e-da5e-4acf-aa24-24355ea076cd' User entered 'No (N)'	System	15 Dec 2020 17:01:31
	System	15 Dec 2020 17:01:31

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-15T12:01:25', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5cd6d97e-da5e-4acf-aa24-24355ea076cd' User entered 'No (N)'	System	15 Dec 2020 17:01:31
	System	15 Dec 2020 17:01:31

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-15T12:01:28', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '5cd6d97e-da5e-4acf-aa24-24355ea076cd' User entered '15 Dec 2020 12:01:28'	System	15 Dec 2020 17:01:31
	System	15 Dec 2020 17:01:31

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-20T15:43:26', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b168b877-4c72-487e-9292-09e8ad03b5d1'	System	20 Dec 2020 20:43:36
User entered 'No (N)'	System	20 Dec 2020 20:43:36

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-20T15:43:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b168b877-4c72-487e-9292-09e8ad03b5d1'	System	20 Dec 2020 20:43:36
User entered 'No (N)'	System	20 Dec 2020 20:43:36

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-20T15:43:32', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b168b877-4c72-487e-9292-09e8ad03b5d1' User entered '20 Dec 2020 15:43:32'	System	20 Dec 2020 20:43:36
	System	20 Dec 2020 20:43:36

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-28T13:05:37', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e0044b05-beb7-49b1-98aa-74f0daac1895'	System	28 Dec 2020 18:05:45
User entered 'No (N)'	System	28 Dec 2020 18:05:45

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-28T13:05:39', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e0044b05-beb7-49b1-98aa-74f0daac1895'	System	28 Dec 2020 18:05:45
User entered 'No (N)'	System	28 Dec 2020 18:05:45

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2020-12-28T13:05:42', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'e0044b05-beb7-49b1-98aa-74f0daac1895' User entered '28 Dec 2020 13:05:42'	System	28 Dec 2020 18:05:45
	System	28 Dec 2020 18:05:45

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-03T17:20:50', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '97022e4a-98d1-46d2-8977-af7986a36a2f' User entered 'No (N)'	System	03 Jan 2021 22:20:59
	System	03 Jan 2021 22:20:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-03T17:20:54', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '97022e4a-98d1-46d2-8977-af7986a36a2f' User entered 'No (N)'	System	03 Jan 2021 22:20:59
	System	03 Jan 2021 22:20:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-03T17:20:57', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '97022e4a-98d1-46d2-8977-af7986a36a2f' User entered '03 Jan 2021 17:20:57'	System	03 Jan 2021 22:20:59
	System	03 Jan 2021 22:20:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-10T15:47:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0438c64d-2efa-4d97-98af-e82bf9ec037e' User entered 'No (N)'	System	10 Jan 2021 20:48:25
	System	10 Jan 2021 20:48:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-10T15:47:50', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0438c64d-2efa-4d97-98af-e82bf9ec037e' User entered 'No (N)'	System	10 Jan 2021 20:48:25
	System	10 Jan 2021 20:48:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-10T15:47:53', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '0438c64d-2efa-4d97-98af-e82bf9ec037e' User entered '10 Jan 2021 15:47:53'	System	10 Jan 2021 20:48:25
	System	10 Jan 2021 20:48:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-17T07:10:01', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7498da84-13ed-45e1-b54d-2964176231ca' User entered 'No (N)'	System	17 Jan 2021 12:10:14
	System	17 Jan 2021 12:10:14

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-17T07:10:05', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7498da84-13ed-45e1-b54d-2964176231ca' User entered 'No (N)'	System	17 Jan 2021 12:10:14

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-17T07:10:09', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '7498da84-13ed-45e1-b54d-2964176231ca' User entered '17 Jan 2021 07:10:09'	System	17 Jan 2021 12:10:14
	System	17 Jan 2021 12:10:14

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-24T07:37:38', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '44c46aed-9c73-46e3-8d8f-df7326eec9ca' User entered 'No (N)'	System	24 Jan 2021 12:37:49
	System	24 Jan 2021 12:37:49

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-24T07:37:41', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '44c46aed-9c73-46e3-8d8f-df7326eec9ca' User entered 'No (N)'	System	24 Jan 2021 12:37:49
	System	24 Jan 2021 12:37:49

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-01-24T07:37:45', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '44c46aed-9c73-46e3-8d8f-df7326eec9ca' User entered '24 Jan 2021 07:37:45'	System	24 Jan 2021 12:37:49

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-02T10:30:13', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '028d0b69-1046-4e5f-9db0-454ba9931efe' User entered 'No (N)'	System	02 Feb 2021 15:30:23
	System	02 Feb 2021 15:30:23

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-02T10:30:15', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '028d0b69-1046-4e5f-9db0-454ba9931efe' User entered 'No (N)'	System	02 Feb 2021 15:30:23
	System	02 Feb 2021 15:30:23

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-02T10:30:17', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '028d0b69-1046-4e5f-9db0-454ba9931efe' User entered '02 Feb 2021 10:30:17'	System	02 Feb 2021 15:30:23
	System	02 Feb 2021 15:30:23

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-07T08:45:53', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '086d8956-000d-469b-98a2-a142c035fb04'	System	07 Feb 2021 13:45:59
User entered 'No (N)'	System	07 Feb 2021 13:45:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-07T08:45:55', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '086d8956-000d-469b-98a2-a142c035fb04'	System	07 Feb 2021 13:45:59
User entered 'No (N)'	System	07 Feb 2021 13:45:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-07T08:45:58', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '086d8956-000d-469b-98a2-a142c035fb04'	System	07 Feb 2021 13:45:59
User entered '07 Feb 2021 08:45:58'	System	07 Feb 2021 13:45:59

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-14T08:21:40', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1840fa21-e9fe-4d05-b4ec-7c45a438bd19' User entered 'No (N)'	System	14 Feb 2021 13:21:47
	System	14 Feb 2021 13:21:47

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-14T08:21:43', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1840fa21-e9fe-4d05-b4ec-7c45a438bd19'	System	14 Feb 2021 13:21:47
User entered 'No (N)'	System	14 Feb 2021 13:21:47

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-14T08:21:45', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '1840fa21-e9fe-4d05-b4ec-7c45a438bd19' User entered '14 Feb 2021 08:21:45'	System	14 Feb 2021 13:21:47
	System	14 Feb 2021 13:21:47

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-21T01:34:22', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '871046bb-8a0c-4413-80e5-a32df1d56126' User entered 'No (N)'	System	21 Feb 2021 06:34:29
	System	21 Feb 2021 06:34:29

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-21T01:34:24', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '871046bb-8a0c-4413-80e5-a32df1d56126' User entered 'No (N)'	System	21 Feb 2021 06:34:29
	System	21 Feb 2021 06:34:29

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-21T01:34:27', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '871046bb-8a0c-4413-80e5-a32df1d56126' User entered '21 Feb 2021 01:34:27'	System	21 Feb 2021 06:34:29
	System	21 Feb 2021 06:34:29

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-28T01:25:29', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'faf58e6e-0f5e-4a4d-9a8e-541d1a2c086c' User entered 'No (N)'	System	28 Feb 2021 06:25:38
	System	28 Feb 2021 06:25:38

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-28T01:25:33', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'faf58e6e-0f5e-4a4d-9a8e-541d1a2c086c' User entered 'No (N)'	System	28 Feb 2021 06:25:38

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-28T01:25:36', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'faf58e6e-0f5e-4a4d-9a8e-541d1a2c086c' User entered '28 Feb 2021 01:25:36'	System	28 Feb 2021 06:25:38
	System	28 Feb 2021 06:25:38

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-07T06:15:18', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'f01755dc-91c4-485b-ac9a-d224256ed280'	System	07 Mar 2021 11:15:26
User entered 'No (N)'	System	07 Mar 2021 11:15:26

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-07T06:15:20', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'f01755dc-91c4-485b-ac9a-d224256ed280'	System	07 Mar 2021 11:15:26
User entered 'No (N)'	System	07 Mar 2021 11:15:26

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-07T06:15:22', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'f01755dc-91c4-485b-ac9a-d224256ed280' User entered '07 Mar 2021 06:15:22'	System	07 Mar 2021 11:15:26
	System	07 Mar 2021 11:15:26

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-14T21:46:41', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '14816019-fccf-4446-94e7-cc998fead836'	System	15 Mar 2021 01:46:49
User entered 'No (N)'	System	15 Mar 2021 01:46:49

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-14T21:46:43', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '14816019-fccf-4446-94e7-cc998fead836'	System	15 Mar 2021 01:46:49
User entered 'No (N)'	System	15 Mar 2021 01:46:49

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-14T21:46:45', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '14816019-fccf-4446-94e7-cc998fead836' User entered '14 Mar 2021 21:46:45'	System	15 Mar 2021 01:46:49

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-21T06:06:26', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '53e18f64-20e7-46ca-ad58-6d82a21136ba' User entered 'No (N)'	System	21 Mar 2021 10:06:32
	System	21 Mar 2021 10:06:32

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-21T06:06:28', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '53e18f64-20e7-46ca-ad58-6d82a21136ba' User entered 'No (N)'	System	21 Mar 2021 10:06:32
	System	21 Mar 2021 10:06:32

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-03-21T06:06:30', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '53e18f64-20e7-46ca-ad58-6d82a21136ba' User entered '21 Mar 2021 06:06:30'	System	21 Mar 2021 10:06:32
	System	21 Mar 2021 10:06:32

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-01T12:18:05', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '63157d70-f865-4e2c-9688-5d3e87e79e33'	System	01 Apr 2021 16:24:42
User entered 'No (N)'	System	01 Apr 2021 16:24:42

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-01T12:18:06', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '63157d70-f865-4e2c-9688-5d3e87e79e33' User entered 'No (N)'	System	01 Apr 2021 16:24:42
	System	01 Apr 2021 16:24:42

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-01T12:18:08', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '63157d70-f865-4e2c-9688-5d3e87e79e33'	System	01 Apr 2021 16:24:42
User entered '01 Apr 2021 12:18:08'	System	01 Apr 2021 16:24:42

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-08T11:02:30', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '41b02956-36f5-4fee-aa46-93cb5c430f97'	System	08 Apr 2021 15:02:42
User entered 'No (N)'	System	08 Apr 2021 15:02:42

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-08T11:02:32', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '41b02956-36f5-4fee-aa46-93cb5c430f97'	System	08 Apr 2021 15:02:42
User entered 'No (N)'	System	08 Apr 2021 15:02:42

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-08T11:02:34', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '41b02956-36f5-4fee-aa46-93cb5c430f97'	System	08 Apr 2021 15:02:42
User entered '08 Apr 2021 11:02:34'	System	08 Apr 2021 15:02:42

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-11T08:56:17', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b919d92a-231e-45b2-972d-2f9012d6f48f' User entered 'No (N)'	System	11 Apr 2021 12:56:27
	System	11 Apr 2021 12:56:27

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-11T08:56:20', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b919d92a-231e-45b2-972d-2f9012d6f48f' User entered 'No (N)'	System	11 Apr 2021 12:56:27
	System	11 Apr 2021 12:56:27

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-11T08:56:23', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b919d92a-231e-45b2-972d-2f9012d6f48f' User entered '11 Apr 2021 08:56:23'	System	11 Apr 2021 12:56:27
	System	11 Apr 2021 12:56:27

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-19T06:51:59', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '17ea806d-a926-4fa3-aa35-281371cf090a' User entered 'No (N)'	System	19 Apr 2021 10:52:05
	System	19 Apr 2021 10:52:05

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-19T06:52:00', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '17ea806d-a926-4fa3-aa35-281371cf090a' User entered 'No (N)'	System	19 Apr 2021 10:52:05

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-19T06:52:02', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '17ea806d-a926-4fa3-aa35-281371cf090a' User entered '19 Apr 2021 06:52:02'	System	19 Apr 2021 10:52:05
	System	19 Apr 2021 10:52:05

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-25T07:46:50', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b8dbc9cc-29a9-4447-866c-ab6ab38d686c' User entered 'No (N)'	System	25 Apr 2021 11:46:56
	System	25 Apr 2021 11:46:56

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-25T07:46:52', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b8dbc9cc-29a9-4447-866c-ab6ab38d686c' User entered 'No (N)'	System	25 Apr 2021 11:46:56
	System	25 Apr 2021 11:46:56

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-04-25T07:46:54', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: 'b8dbc9cc-29a9-4447-866c-ab6ab38d686c' User entered '25 Apr 2021 07:46:54'	System	25 Apr 2021 11:46:56
	System	25 Apr 2021 11:46:56

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-05-02T22:49:41', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '41f24c2d-12f7-44cd-bd78-c7a413f43395'	System	03 May 2021 02:52:25
User entered 'No (N)'	System	03 May 2021 02:52:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

Have you been exposed to someone with 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 (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-05-02T22:49:43', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '41f24c2d-12f7-44cd-bd78-c7a413f43395'	System	03 May 2021 02:52:25
User entered 'No (N)'	System	03 May 2021 02:52:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-05-02T22:49:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '41f24c2d-12f7-44cd-bd78-c7a413f43395'	System	03 May 2021 02:52:25
User entered '02 May 2021 22:49:46'	System	03 May 2021 02:52:25

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 11:31:55

US3152426

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:09:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:31:55
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 11:31:55

US3152426

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:09:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:00:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-28T01:25:46', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '34445550-284c-4692-a1d0-7860b8f92a2e' User entered 'No (N)'	System	28 Feb 2021 06:26:06
	System	28 Feb 2021 06:26:06

US3152426

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:09:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:00:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4D6D6CA-2135-472E-8235-1A0AF72199E2)', Time: '2021-02-28T01:26:03', User OID: 'PatientReportedOutcome (US3152426)', ODM File OID: '34445550-284c-4692-a1d0-7860b8f92a2e' User entered '28 Feb 2021 01:26:03'	System	28 Feb 2021 06:26:06
	System	28 Feb 2021 06:26:06

US3152426

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:56
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:35:47
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	28 Dec 2020 18:10:50

US3152426

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:56
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:35:47
User entered '28 Dec 2020'	Tanya Alexander (b) (4)	28 Dec 2020 18:10:50

US3152426

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:56
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:35:47
User entered 'Contact Made (CONTACT MADE)'	Tanya Alexander (b) (4)	28 Dec 2020 18:10:50

US3152426

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:56
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:35:47
User entered empty.	Tanya Alexander (b) (4)	28 Dec 2020 18:10:50

US3152426

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:51
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:35:54
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	28 Dec 2020 18:10:55

US3152426

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:01:36
User entered 'I'	System	28 Dec 2020 18:10:55

US3152426

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:21:14
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:14:51

US3152426

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User closed query 'per source 26jan21 @1632. Please review and update' (Site from CRA).	(b) (4), (b) (6)	10 Apr 2021 19:55:30
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:55:29
Query 'per source 26jan21 @1632. Please review and update' answered with 'updated, thanks ' (Site from CRA).	Jemario Blackwell (b) (4)	03 Apr 2021 20:01:12
User entered '26 Jan 2021' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	03 Apr 2021 20:00:54
User opened query 'per source 26jan21 @1632. Please review and update' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:21:13
User entered '25 Jan 2021'	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:14:51

US3152426

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:21:16
User entered 'Contact Made (CONTACT MADE)'	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:14:51

US3152426

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:21:17
User entered empty.	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:14:51

US3152426

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:21:30
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:14:55

US3152426

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User entered 'I'	System	25 Feb 2021 19:14:55

US3152426

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:23:56
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	01 Mar 2021 14:55:34

US3152426

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User closed query '26feb21 @1557 per source . Please review and update' (Site from CRA).	(b) (4), (b) (6)	10 Apr 2021 19:55:45
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:55:43
Query '26feb21 @1557 per source . Please review and update' answered with 'updated, thanks ' (Site from CRA).	Jemario Blackwell (b) (4)	06 Apr 2021 18:26:15
User entered '26 Feb 2021' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	06 Apr 2021 18:25:54
User opened query '26feb21 @1557 per source . Please review and update' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:23:49
User entered '1 Mar 2021'	Priscilla Buahin (b) (4)	01 Mar 2021 14:55:34

US3152426

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:23:52
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	01 Mar 2021 14:55:34

US3152426

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:23:54
User entered empty.	Priscilla Buahin (b) (4)	01 Mar 2021 14:55:34

US3152426

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:24:13
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	01 Mar 2021 14:55:39

US3152426

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User entered 'I'	System	01 Mar 2021 14:55:39

US3152426

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:55:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 15:41:53

US3152426

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:55:34
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 15:41:53

US3152426

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:55:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Mar 2021 15:41:53

US3152426

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:55:34
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 15:41:53

US3152426

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:55:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 15:41:59

US3152426

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:31
User entered 'I'	System	26 Mar 2021 15:41:59

US3152426

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:25

US3152426

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered '14 Apr 2021'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:25

US3152426

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'Clinic (Clinic)'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:25

US3152426

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 14:54:25

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'No (N)'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 14:54:30

US3152426

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'No (N)'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:36

US3152426

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered empty.	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:36

US3152426

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:49

US3152426

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered '14 Apr 2021'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:49

US3152426

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered '07:47'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:49

US3152426

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '14 Apr 2021 07:47'	System	14 Apr 2021 14:54:49

US3152426

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:54

US3152426

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 14:54:54

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:40:41
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:07:58

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:40:41
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:07:58

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:40:41
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	08 Jan 2021 14:07:58

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 14:07:58

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:21:33

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:21:33

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
User entered 'Placebo (Placebo)'	Devan Myers (b) (4)	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:49:56
User entered 'Placebo (Placebo)'	Devan Myers (b) (4)	08 Jan 2021 14:08:12
	(b) (4)	

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:49:56
User entered 'Placebo (Placebo)'	Devan Myers (b) (4)	08 Jan 2021 14:08:12
	(b) (4)	

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:42:05
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '1'	System	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:09:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'I'	System	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered missing code ND - Not Done.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered missing code ND - Not Done.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered empty.	System	08 Jan 2021 15:11:43
DataPoint set to visible.	System	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered missing code ND - Not Done.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered missing code ND - Not Done.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered empty.	System	08 Jan 2021 15:11:43
DataPoint set to visible.	System	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User accepted default value 'Pre-Dose (PREDOSE)'	Devan Myers (b) (4) (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '08:15'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '8 Jan 2021 08:15'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '37.0' C	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered 'Oral (Oral)'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '99'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'bpm'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '14'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'breaths/min'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '120'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'mmHg'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '81'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'mmHg'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered missing code ND - Not Done.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered missing code ND - Not Done.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:09:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered empty.	System	08 Jan 2021 15:11:43
DataPoint set to visible.	System	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User accepted default value 'Post-Dose (POSTDOSE)'	Devan Myers (b) (4) (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '09:23'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '8 Jan 2021 09:23'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '36.9' C	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered 'Oral (Oral)'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '82'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'bpm'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '14'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'breaths/min'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '120'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'mmHg'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:45
User entered '90'	Devan Myers (b) (4)	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'mmHg'	System	08 Jan 2021 15:11:43

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:55
User entered 'No (N)'	Devan Myers (b) (4)	08 Jan 2021 14:08:22

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:43:55
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 14:08:22

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered 'Urine (URINE)'	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered 'Negative (NEGATIVE)'	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered 'No (N)'	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:44:46
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered empty.	System	08 Jan 2021 14:08:34

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered empty.	Devan Myers (b) (4)	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'mRNA-1273'	System	08 Jan 2021 14:09:52
DataPoint set to visible.	System	08 Jan 2021 14:08:12

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered '08:53'	Devan Myers (b) (4)	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '8 Jan 2021 08:53'	System	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:05
User entered 'ONCE'	System	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 14:09:52

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:11
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:10:10

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:11
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:10:10

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:11
User entered '07:47'	Devan Myers (b) (4)	08 Jan 2021 14:10:10

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '8 Jan 2021 07:47'	System	08 Jan 2021 14:10:10

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:32
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:10:26

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:32
User entered '8 Jan 2021'	Devan Myers (b) (4)	08 Jan 2021 14:10:26

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:32
User entered '07:52'	Devan Myers (b) (4)	08 Jan 2021 14:10:26

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:09:36

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '8 Jan 2021 07:52'	System	08 Jan 2021 14:10:26

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:45:37
User entered 'Yes (Y)'	Devan Myers (b) (4)	08 Jan 2021 14:10:32

US3152426

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:22:44
User entered '1'	System	08 Jan 2021 14:10:32

US3152426

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:47:10
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	21 Jan 2021 14:48:39
	(b) (4)	

US3152426

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:47:10
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 16:25:47
Comment added 'response to query should read, multiple attempts made starting 15 Jan 2021 total of 5 attempts made call completed with subject 21 Jan 2021'.	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:13:02
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple a 15 Jan 2021' (Site from System).	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:11:34
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 01:51:56
User entered '21 Jan 2021'	Jemario Blackwell (b) (4)	21 Jan 2021 14:48:39

US3152426

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:47:10
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	21 Jan 2021 14:48:39
	(b) (4)	

US3152426

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:47:10
User entered empty.	Jemario Blackwell (b) (4)	21 Jan 2021 14:48:39
	(b) (4)	

US3152426

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:52:11
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	21 Jan 2021 14:48:48
	(b) (4)	

US3152426

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User entered 'I'	System	21 Jan 2021 14:48:48

US3152426

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:11
User entered 'I'	System	21 Jan 2021 14:48:48
DataPoint set to visible.	System	21 Jan 2021 14:48:48

US3152426

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:17:04
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	09 Apr 2021 18:21:44
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:17:43

US3152426

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 08:58:21
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'OL-D29 was completed out of window and post OL-D57 on 09Apr2021. Subject was previously excluded from dose 2 on account of pregnancy. Subject requested to be given dose for full protection 2 despite pregnancy. Epip approved dose 2 per PI decision.' (Site from System).	Priscilla Buahin (b) (4)	14 Apr 2021 14:52:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:17:04
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Apr 2021 18:21:44
User entered '9 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	09 Apr 2021 18:21:44
User entered empty.	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:17:43

US3152426

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:17:04
User entered 'Clinic (Clinic)' reason for change: New Information	(b) (4), (b) (6)	09 Apr 2021 18:21:44
User entered empty.	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 19:17:43

US3152426

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'OLD29'	System	25 Feb 2021 19:17:43

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '13:18'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered '9 Apr 2021 13:18'	System	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '36.9' C	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '72'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'bpm'	System	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '16'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'breaths/min'	System	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '126'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'mmHg'	System	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '85'	(b) (4), (b) (6)	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'mmHg'	System	09 Apr 2021 18:21:04

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '14:38'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered '9 Apr 2021 14:38'	System	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '36.6' C	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '62'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'bpm'	System	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '16'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'breaths/min'	System	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '112'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'mmHg'	System	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:30
User entered '72'	(b) (4), (b) (6)	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'mmHg'	System	09 Apr 2021 18:51:48

US3152426

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:43
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 18:19:28

US3152426

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:43
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:28

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:21:55
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered empty.	System	09 Apr 2021 18:19:40

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'mRNA-1273'	System	09 Apr 2021 18:20:04
DataPoint set to visible.	System	21 Jan 2021 14:48:48

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered '14:08'	(b) (4), (b) (6)	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered '9 Apr 2021 14:08'	System	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:13
User entered 'ONCE'	System	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:09:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 18:20:04

US3152426

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:17:23
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	05 Mar 2021 12:15:34

US3152426

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:13:04
User entered 'I'	System	05 Mar 2021 12:15:34

US3152426

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:20:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User closed query 'Per CDM: Based on your response of "SC was not conducted" please consider removing all the data from this form.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 11:39:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:40:31
Query 'Per CDM: Based on your response of "SC was not conducted" please consider removing all the data from this form.' answered with 'Safety call was completed 7 days after dose 2 as per protocol. Dose 2 was however received out of window due to positive pregnancy test.' (Site from DM).	Priscilla Buahin (b) (4) (b) (4)	22 Apr 2021 14:34:01
DataPoint Un-verified.	Priscilla Buahin (b) (4) (b) (4)	22 Apr 2021 14:32:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Priscilla Buahin (b) (4) (b) (4)	22 Apr 2021 14:32:16
User opened query 'Per CDM: Based on your response of "SC was not conducted" please consider removing all the data from this form.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 21:57:58
Query 'Per CDM: Select one status for the follow-up contact has been provided yet "Was Contact Attempted" is blank. Please confirm whether or not this SC took place. If so, please provide a response to this question or else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 21:57:07
User opened query 'Per CDM: Select one status for the follow-up contact has been provided yet "Was Contact Attempted" is blank. Please confirm whether or not this SC took place. If so, please provide a response to this question or else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 21:55:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:57
DataPoint Un-verified.		12 Apr 2021 14:22:43
DataPoint Verified.		23 Mar 2021 15:55:31
User closed query 'Data is required. Please complete.' (Site from System).		09 Mar 2021 03:12:50

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EAB) (1725)

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered with 'Subject did not receive vaccine so safety call was not conducted. See unscheduled visit' (Site from System).	Tanya Alexander (b) (4)	05 Mar 2021 12:20:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 12:19:44
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	05 Mar 2021 12:19:44
User entered empty; reason for change Data Entry Error	Tanya Alexander (b) (4)	05 Mar 2021 12:19:44
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	05 Mar 2021 12:19:31
User entered 'No (N)'	Tanya Alexander (b) (4)	05 Mar 2021 12:19:31

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:20:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:40:34
DataPoint Un-verified.	Priscilla Buahin (b) (4)	22 Apr 2021 14:32:16
User entered '17 Apr 2021' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	22 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:57
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:42
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:55:31
User entered empty.	Tanya Alexander (b) (4)	05 Mar 2021 12:19:31

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:20:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:40:36
DataPoint Un-verified.	Priscilla Buahin (b) (4)	22 Apr 2021 14:32:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Priscilla Buahin (b) (4)	22 Apr 2021 14:32:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:46:57
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:40
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:55:31
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Tanya Alexander (b) (4)	05 Mar 2021 12:19:31
	(b) (4)	

US3152426

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:09:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:20:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:40:38
DataPoint Un-verified.	Priscilla Buahin (b) (4)	22 Apr 2021 14:32:16
User entered 'SUBJECT received dose 2 outside of window. Safety call Day 36 conducted within window per protocol.' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	22 Apr 2021 14:32:16
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:57
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 14:22:33
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:55:31
User entered 'Subject did not receive vaccine'	Tanya Alexander (b) (4)	05 Mar 2021 12:19:31

US3152426

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:20:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 15:55:41
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	05 Mar 2021 12:16:07

US3152426

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:09:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:20:31
User entered 'I'	System	05 Mar 2021 12:16:07

US3152426

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:29
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	05 Mar 2021 12:16:18

US3152426

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 08:58:38
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'OL-D57 was completed on 05Mar2021 before OL-D29 which was completed out of window on 09Apr2021 because Subject was previously excluded from dose 2 on account of pregnancy. Subject requested to be given dose for full protection 2 despite pregnancy. Epip approved dose 2 per PI decision. ' (Site from System).	Priscilla Buahin (b) (4)	14 Apr 2021 14:54:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:29
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Apr 2021 18:20:04
User entered '5 Mar 2021'	Tanya Alexander (b) (4)	05 Mar 2021 12:16:18

US3152426

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:29
User entered 'Clinic (Clinic)'	Tanya Alexander (b) (4)	05 Mar 2021 12:16:18

US3152426

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:09:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered 'OLD57'	System	05 Mar 2021 12:16:18

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '5 Mar 2021'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '07:08'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered '5 Mar 2021 07:08'	System	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '36.9' C	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered 'Oral (Oral)'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered empty.	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '76'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered 'bpm'	System	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '14'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered 'breaths/min'	System	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '109'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered 'mmHg'	System	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:30
User entered '65'	Tanya Alexander (b) (4)	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered 'mmHg'	System	05 Mar 2021 12:17:04

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14

US3152426

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:09:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14

US3152426

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:42
User entered 'No (N)'	Tanya Alexander (b) (4)	05 Mar 2021 12:18:12

US3152426

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:09:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:42
User entered empty.	Tanya Alexander (b) (4)	05 Mar 2021 12:18:12

US3152426

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:13
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	05 Mar 2021 12:18:50

US3152426

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:13
User entered '5 Mar 2021'	Tanya Alexander (b) (4)	05 Mar 2021 12:18:50

US3152426

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:13
User entered '07:01'	Tanya Alexander (b) (4)	05 Mar 2021 12:18:50

US3152426

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:09:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:50:14
User entered '5 Mar 2021 07:01'	System	05 Mar 2021 12:18:50

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:36

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:35
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:36:23
User entered '10 Feb 2021'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:03

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:36

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:35
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:36:23
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:03

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:36

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:35
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:36:23
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:03

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:36

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:35
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:36:23
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:03

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:09:36

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:35
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:36:23
User entered 'I'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:03

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User entered '10 Feb 2021'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User entered 'Urine (URINE)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 16:33:12
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'pregnancy test confirmed positive pregnancy form submitted 10 feb 2021 ' (Site from System).	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:30:24
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	10 Feb 2021 21:29:29
User entered 'Positive (POSITIVE)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:43:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:37:11
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:29:29

US3152426

Folder: Unscheduled 10 Feb 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:09:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:31
User entered empty.	System	10 Feb 2021 21:29:29

US3152426

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:09:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:21
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:39:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 17:59:01

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 05:43:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 05:43:40
Data point term sent to Coder	System	16 Oct 2020 18:01:45
User entered 'Fatigue'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User closed query 'Per DM CLR: RQ: Response noted, however, response reverted to Yes again. Please note that this symptom is not recorded in the eDiary, thus this is a unsolicited adverse reaction. Please update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:02:51
Query 'Per DM CLR: RQ: Response noted, however, response reverted to Yes again. Please note that this symptom is not recorded in the eDiary, thus this is a unsolicited adverse reaction. Please update the response as appropriate. Otherwise, clarify.' answered with 'it is a solicited AE it occurred during diary solicitation period subject however missed entries for day 1 evening and Day 2. hence why fatigue was captured on ae log. ' (Site from DM).	Oyebisi Olanrewaju (b) (4)	25 Feb 2021 20:13:29
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:38:47
User closed query 'Source has Solicited Adverse Reaction checked. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 19:38:32
User opened query 'Per DM CLR: RQ: Response noted, however, response reverted to Yes again. Please note that this symptom is not recorded in the eDiary, thus this is a unsolicited adverse reaction. Please update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:14:03
Query 'Source has Solicited Adverse Reaction checked. Please review and reconcile. ' answered with 'Updated' (Site from CRA).	Priscilla Buahin (b) (4)	23 Nov 2020 21:28:54
DataPoint Un-verified.	Priscilla Buahin (b) (4)	23 Nov 2020 21:28:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	23 Nov 2020 21:28:47
User opened query 'Source has Solicited Adverse Reaction checked. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:41:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 09:51:59
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.	(b) (4), (b) (6)	12 Nov 2020 20:31:02
' answered with 'Updated, AE is NOT solicited AE. Data has been corrected to reflect such' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:27:51
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.	(b) (4), (b) (6)	05 Nov 2020 11:11:44
' (Site from DM).		
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '03 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '09:00'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User entered '03 Oct 2020 09:00'	System	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '04 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '09:00'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User entered '04 Oct 2020 09:00'	System	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Related (RELATED)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'l'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Subject forgot to enter Day 2 e-diary entries. On safety follow up phone call, reported fatigue on Day 2 that resolved by Day 3.'	(b) (4), (b) (6)	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User entered '0'	System	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11
User entered '0'	System	16 Oct 2020 18:01:32

US3152426

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:09:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:11

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 05:51:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 05:51:01
Data point term sent to Coder	System	16 Oct 2020 18:03:48
User entered 'Back Pain'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '09 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User entered empty.	System	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '13 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User entered empty.	System	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 18:03:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:03:49
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 18:03:39
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:20
User entered 'Subject reported mild back soreness on 7 day safety follow up phone call. Did not take medication. Attributed to how she slept but unsure. Resolved on 13 Oct 2020. Never took medication or sought medical attention.'	(b) (4), (b) (6)	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User entered '0'	System	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15
User entered '0'	System	16 Oct 2020 18:03:39

US3152426

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:09:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:27:15

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 21:33:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 21:33:42
Data point term sent to Coder	System	10 Feb 2021 21:32:30
User entered 'worsening gastroesophageal reflux disease'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '27 Jan 2021'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'None (NONE)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Feb 2021 21:31:46
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Feb 2021 21:31:37
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	22 Mar 2021 06:23:55
	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'ConMed log updated.' (Site from DM).	Azure Erskine (b) (4)	18 Mar 2021 13:47:01
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 22:12:19
User entered '1' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:46
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered '0'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:58:47
User signature succeeded.	Shishir Khetan (b) (4)	21 Mar 2021 14:03:58
User entered empty.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 21:31:37

US3152426

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:09:36

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 21:31:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:09:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:03:21
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:32
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Oct 2020 19:51:18

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:53:48
Data point term sent to Coder	System	02 Oct 2020 19:52:20
User entered 'Multivitamin'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User closed query 'Per DM CLR: Indication for medication is reportd as NUTRITIONAL SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:41:44
Query 'Per DM CLR: Indication for medication is reportd as NUTRITIONAL SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' answered with 'updated ' (Site from DM).	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:38:50
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:38:47
User entered 'Yes (Y)' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:38:47
User opened query 'Per DM CLR: Indication for medication is reportd as NUTRITIONAL SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:34:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Nutritional Supplement'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'I'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'tablet (TABLET)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'once daily (QD)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Oral (ORAL)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'UN Jan 2020'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '0'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:52:12

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:53:49
Data point term sent to Coder	System	02 Oct 2020 19:53:21
User entered 'Vitamin C'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User closed query 'Per DM CLR: Indication for medication is reportd as NUTRITIONAL SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:42:07
Query 'Per DM CLR: Indication for medication is reportd as NUTRITIONAL SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' answered with 'updated ' (Site from DM).	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:39:23
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:39:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	10 Feb 2021 21:39:11
User opened query 'Per DM CLR: Indication for medication is reportd as NUTRITIONAL SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:35:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Nutritional Supplement'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 2000 IU) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:42:15
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 2000 IU) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'clarified and updated ' (Site from DM).	Oyebisi Olanrewaju (b) (4)	11 Feb 2021 18:23:46
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	11 Feb 2021 18:23:33
User entered '500' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	11 Feb 2021 18:23:33
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 2000 IU) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:34:28
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '1'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Un-verified.	Oyebisi Olanrewaju	11 Feb 2021 18:23:33
User entered 'mg (mg)' reason for change: New Information	(b) (4)	11 Feb 2021 18:23:33
DataPoint Verified.	(b) (4)	19 Nov 2020 18:45:46
User entered 'tablet (TABLET)'	Devan Myers (b) (4)	02 Oct 2020 19:53:02
	(b) (4)	

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'once daily (QD)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Oral (ORAL)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '28 Sep 2020'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '0'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:53:02

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:55:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:55:49
Data point term sent to Coder	System	02 Oct 2020 19:55:24
User entered 'Vitamin D'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Vitamin D deficiency'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:42:48
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'dose unknown ' (Site from DM).	Oyebisi Olanrewaju (b) (4)	11 Feb 2021 18:24:05
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:36:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'I'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'tablet (TABLET)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'once daily (QD)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Oral (ORAL)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'UN Jan 2020'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '0'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:54:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: HERBAL NUTRIENTS, PRODUCT: LINUM USITATISSIMUM SEED OIL, PRODUCTSYNONYM: FLAX SEED OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 17:41:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 17:41:02
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: HERBAL NUTRIENTS, PRODUCT: LINUM USITATISSIMUM SEED OIL, PRODUCTSYNONYM: FLAX SEED OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 17:26:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 17:26:03
Data point term sent to Coder Coding entries removed.	System	19 Nov 2020 17:25:29
	Priscilla Buahin (b) (4)	19 Nov 2020 17:25:16
User entered 'FLAX SEED oil' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	19 Nov 2020 17:25:16
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: LINUM USITATISSIMUM SEED, PRODUCTSYNONYM: FLAXSEED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:57:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:57:51
Data point term sent to Coder	System	02 Oct 2020 19:56:27
User entered 'Flax Seed'	Devan Myers (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 22:50:48
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Tanya Alexander (b) (4) (b) (4)	28 Dec 2020 17:25:40
DataPoint Un-verified.	Tanya Alexander (b) (4) (b) (4)	28 Dec 2020 17:25:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Tanya Alexander (b) (4) (b) (4)	28 Dec 2020 17:25:25
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:23:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Nutritional Supplement'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'I'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'capsule (CAPSULE)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'once daily (QD)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Oral (ORAL)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '28 Sep 2020'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '0'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:55:34

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 13:30:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 13:30:34
Data point term sent to Coder Coding entries removed.	System Devan Myers (b) (4) (b) (4)	21 Oct 2020 13:29:28 21 Oct 2020 13:29:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:58:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:58:52
Data point term sent to Coder User entered 'Ibuprofen'	System Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:57:28 02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:52:47
Query 'Per MM: Please clarify indication.' answered with 'updated accordingly' (Site from DM).	Devan Myers (b) (4)	21 Oct 2020 13:29:26
User entered 'Migraines' reason for change: Data Entry Error	Devan Myers (b) (4)	21 Oct 2020 13:29:16
User opened query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:20:59
User entered 'Medical History'	Devan Myers (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '200'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'mg (mg)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'as needed (PRN)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Oral (ORAL)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'UN UNK 1997'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered '0'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:45:46
User entered 'No (N)'	Devan Myers (b) (4) (b) (4)	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:56:42

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 13:47:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 13:47:38
Data point term sent to Coder	System	18 Mar 2021 13:46:44
User entered 'pantoprazole'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'No (N)'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'worsening GERD'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered '40'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'mg (mg)'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered empty.	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'once daily (QD)'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered empty.	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'Oral (ORAL)'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered empty.	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered '27 Jan 2021'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered '0'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'Yes (Y)'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered empty.	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:00:28
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'No (N)'	Azure Erskine (b) (4)	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 13:46:15

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: VITAMINS, OTHER COMBINATIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 11:17:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 11:17:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: VITAMINS, OTHER COMBINATIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 11:14:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 11:14:12
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
Data point term sent to Coder	System	13 Apr 2021 15:20:28
User entered 'Megafood blood builder (vitamin C 15mg, folate 600mcg, vitamin B12 30mcg, iron bisalicylate 20mg, beet root 125mg)'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'No (N)'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'iron deficiency anemia'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered '27 Jan 2021'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:34:40
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 15:20:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 15:20:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 15:20:25
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 15:20:16
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 15:20:16

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 20:56:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 20:56:54
Data point term sent to Coder	System	15 Apr 2021 20:55:42
User entered 'vitamin D'	Priscilla Buahin (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:13
User entered 'No (N)'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:15
User entered 'vitamin D deficiency'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:17
User entered '50,000'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:19
User entered 'IU (IU)'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:20
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:28
User entered 'once daily (QD)'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:29
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:33
User entered 'Oral (ORAL)'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:35
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:38
User entered '27 Jan 2021'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:40
User entered '0'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:42
User entered 'Yes (Y)'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:45
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:46
User entered 'No (N)'	Priscilla Buahin (b) (4) (b) (4)	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:09:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 20:54:58

US3152426

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:09:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 13:57:22
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 18:18:04