

US3152175 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:28:53

All time stamps listed in this document are displayed in GMT

US3152175

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 17:15:14

Generated On: 09 Jun 2021 15:28:53

Participant ID

US3152175

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

US3152175

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Date of Informed Consent (*dd MMM yyyy*) 13 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

Condition	RIGHT BUNDLE BRANCH BLOCK
Start date (dd MMM yyyy)	02 MAY 2018
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)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

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 (3)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 04:33:27

Generated On: 09 Jun 2021 15:28:53

Condition	CARDIAC MURMUR
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:15 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 16:15
Height (<i>xxx.x</i>)	151.5 cm
Weight (<i>xxx.x</i>)	60.4 kg
BMI (<i>xxx.x</i>)	26.31550 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 AUG 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) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*) 13 AUG 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*) UN UNK 2007

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: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 04:33:28

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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) 17 Feb 2021 04:33:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 13 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

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

What was the participant's randomization number? 104056

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) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

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) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

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 (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:15 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 16:15
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Height	ND - Not Done
Weight	ND - Not Done
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 (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	18:31 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 18:31
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Was study treatment given? Yes
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 18:00 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 18:00

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) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 13 AUG 2020

Collection time (*00:00-23:59*) 16:40 (24 HR)

Collection date and time (derived) 13 AUG 2020 16:40

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

Collection date (<i>dd MMM yyyy</i>)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:17	13 AUG 2020 17:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:28

Generated On: 09 Jun 2021 15:28:53

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: 09 Jun 2021 15:28:53

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 13 AUG 2020 18:32

PC Open Date & Time 13 AUG 2020 18:20

PC Close Date & Time 13 AUG 2020 20:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

PC Time Stamp	13 AUG 2020 21:59
PC Open Date & Time	13 AUG 2020 21:45
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 19:09
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 AUG 2020 15:51
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 AUG 2020 23:28
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 AUG 2020 13:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

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

PC Time Stamp	19 AUG 2020 15:31
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 AUG 2020 18:31

PC Open Date & Time

13 AUG 2020 18:20

PC Close Date & Time

13 AUG 2020 20:50

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 AUG 2020 21:59

PC Open Date & Time

13 AUG 2020 21:45

PC Close Date & Time

14 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 2

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

14 AUG 2020 19:09

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	15 AUG 2020 12:02
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 AUG 2020 15:51

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 AUG 2020 23:28

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

18 AUG 2020 13:18

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

19 AUG 2020 15:31

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

No
Yes

PC Time stamp	13 AUG 2020 18:34
PC Open Date & Time	13 AUG 2020 18:20
PC Close Date & Time	13 AUG 2020 20:50

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

No

Yes

PC Time stamp	13 AUG 2020 22:00
PC Open Date & Time	13 AUG 2020 21:45
PC Close Date & Time	14 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 19:10
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 12:02
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 15:52
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 23:28
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	18 AUG 2020 13:18
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	19 AUG 2020 15:31
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3152175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 AUG 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:33:16

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 AUG 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:16

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 4 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

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 (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:55 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:55
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

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 (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:23 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:23
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3152175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Was study treatment given? Yes No

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 15:53 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 15:53

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

US3152175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 11 SEP 2020

Collection time (*00:00-23:59*) 15:02 (24 HR)

Collection date and time (derived) 11 SEP 2020 15:02

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:22	11 SEP 2020 15:22
Nasopharyngeal Swab 2	No		

US3152175

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:29

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp 11 SEP 2020 16:23
PC Open Date & Time 11 SEP 2020 16:13
PC Close Date & Time 11 SEP 2020 18:43

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp 11 SEP 2020 19:44
PC Open Date & Time 11 SEP 2020 19:38
PC Close Date & Time 12 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

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

PC Time Stamp	12 SEP 2020 20:25
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 15:50
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 SEP 2020 20:10
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 12:52
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 12:27
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 16:51
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	11 SEP 2020 16:24
PC Open Date & Time	11 SEP 2020 16:13
PC Close Date & Time	11 SEP 2020 18:43

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 SEP 2020 19:44

PC Open Date & Time

11 SEP 2020 19:38

PC Close Date & Time

12 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	12 SEP 2020 20:26
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	13 SEP 2020 15:50
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

14 SEP 2020 20:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

15 SEP 2020 12:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

16 SEP 2020 12:28

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 SEP 2020 16:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

No

Yes

PC Time stamp	11 SEP 2020 16:24
PC Open Date & Time	11 SEP 2020 16:13
PC Close Date & Time	11 SEP 2020 18:43

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

No

Yes

PC Time stamp	11 SEP 2020 19:44
PC Open Date & Time	11 SEP 2020 19:38
PC Close Date & Time	12 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 20:26
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 15:51
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 20:10
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 12:53
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 12:28
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 16:51
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3152175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 SEP 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:17

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:43:24

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 OCT 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:43:24

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:33:30

Generated On: 09 Jun 2021 15:28:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 OCT 2020

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

Folder OID VISIT3

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:33:30

Generated On: 09 Jun 2021 15:28:53

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 08 OCT 2020

Time of assessment (*00:00-23:59*) 14:00 (24 HR)

Vital Signs Date and Time (derived) 08 OCT 2020 14:00

Temperature (*xxx.x*) 37.3 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) 62 beats/min

Pulse units BPM

Respiratory Rate (*xxx*) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) 115 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) 71 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3152175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:33:30

Generated On: 09 Jun 2021 15:28:53

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.

US3152175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:33:30

Generated On: 09 Jun 2021 15:28:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 08 OCT 2020

Collection time (*00:00-23:59*) 14:17 (24 HR)

Collection date and time (derived) 08 OCT 2020 14:17

US3152175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:33:30

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 13 OCT 2020 18:45:21

Patient Cloud Open Date & Time 13 OCT 2020 00:01

Patient Cloud Close Date & Time 17 OCT 2020 23:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 20 OCT 2020 05:45:41

Patient Cloud Open Date & Time 20 OCT 2020 00:01

Patient Cloud Close Date & Time 24 OCT 2020 23:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 78

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 27 OCT 2020 13:57:09

Patient Cloud Open Date & Time 27 OCT 2020 00:01

Patient Cloud Close Date & Time 31 OCT 2020 23:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 92

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 11 NOV 2020 00:06:56

Patient Cloud Open Date & Time 10 NOV 2020 00:01

Patient Cloud Close Date & Time 14 NOV 2020 23:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 99
Have 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	17 NOV 2020 16:11:57
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 NOV 2020 06:27:30
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 NOV 2020 20:04:40
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 17:06:33
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 DEC 2020 23:30:57
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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	19 DEC 2020 12:17:42
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 DEC 2020 18:16:20
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 JAN 2021 14:03:21
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 JAN 2021 08:29:55
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 JAN 2021 08:46:09
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 23 JAN 2021 14:06:34

Patient Cloud Open Date & Time 23 JAN 2021 00:01

Patient Cloud Close Date & Time 27 JAN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	30 JAN 2021 07:07:00
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 FEB 2021 10:49:36
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 FEB 2021 09:39:07
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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	20 FEB 2021 19:04:58
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 FEB 2021 19:53:34
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have you experienced any new COVID-19 disease symptoms 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):	
Have you 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 checked="" 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 checked="" type="radio"/>
Date and time of submission	06 MAR 2021 09:30:54
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 MAR 2021 10:02:16
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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 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 MAR 2021 10:59:27
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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 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	27 MAR 2021 14:41:24
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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 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	04 APR 2021 00:18:17
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 11 APR 2021 09:28:59

Patient Cloud Open Date & Time 10 APR 2021 00:01

Patient Cloud Close Date & Time 14 APR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 APR 2021 16:42:27
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 APR 2021 11:38:01
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 341

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 411

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 06 OCT 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 27 OCT 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 460

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 08 DEC 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 15 DEC 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 29 DEC 2021 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 26 JAN 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	02 MAR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 600

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 06 APR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 621

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#) 17 AUG 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 754

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

DAY 796

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:28:53

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 19:53:48

US3152175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 12:55:50

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 NOV 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:55:50

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 DEC 2020

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 FEB 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID VISIT4

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

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) _____

US3152175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

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.

US3152175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 09:31 (24 HR)

Collection date and time (derived) 22 MAR 2021 09:31

US3152175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 6 APR 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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 _____

US3152175

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3152175

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:53

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"/>

US3152175

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:28:53

Generate Next COVID-19 Assessment

Yes

No

US3152175

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 DEC 2020

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

Folder OID UNBLND_DECIDE

US3152175

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	30 DEC 2020
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>)	30 DEC 2020
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

US3152175

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Height	147.5 cm
Weight	63.5 kg
BMI (xxx.x)	29.18702

US3152175

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Height	147.5 cm
Weight	63.5 kg
BMI (xxx.x)	29.18702
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 DEC 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	30 DEC 2020 15:40
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)	63 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

US3152175

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

Height	147.5 cm
Weight	63.5 kg
BMI (xxx.x)	29.18702
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 DEC 2020
Time of assessment (00:00-23:59)	16:40 (24 HR)
Vital Signs Date and Time (derived)	30 DEC 2020 16:40
Temperature (xxx.x)	36.8 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3152175

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

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.

US3152175

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

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) 30 DEC 2020

What was the treatment time? (00:00-23:59) 16:10 (24 HR)

Treatment Date and Time (derived) 30 DEC 2020 16:10

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

What was the frequency of the study treatment dosing? ONCE

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

US3152175

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 DEC 2020
Collection time (<i>00:00-23:59</i>)	15:46 (24 HR)
Collection date and time (derived)	30 DEC 2020 15:46

US3152175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 DEC 2020

Collection time (*00:00 - 23:59*) 16:04

Collection Date and Time (derived) 30 DEC 2020 16:04

US3152175

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 JAN 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 JAN 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

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

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 (<i>dd MMM yyyy</i>)	26 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	14:13 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 14:13
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

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 (<i>dd MMM yyyy</i>)	26 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	15:15 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 15:15
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

26 JAN 2021

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

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Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 17:15:14

Generated On: 09 Jun 2021 15:28:53

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) 26 JAN 2021

What was the treatment time? (00:00-23:59) 14:45 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 14:45

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 17:15:14

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3152175

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 FEB 2021

Please select one status for the follow-up contact Contact Made
Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3152175

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:15:48

Generated On: 09 Jun 2021 15:28:53

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 MAR 2021

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

Folder OID OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:24 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 09:24
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3152175

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

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.

US3152175

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:15:15

Generated On: 09 Jun 2021 15:28:53

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 09:31 (24 HR)

Collection date and time (derived) 22 MAR 2021 09:31

US3152175

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Mar 2021 02:03:13

Generated On: 09 Jun 2021 15:28:53

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

AEID USA-US073-2021-MRNA-1273-P30
1000009

Adverse event CHOLECYSTITIS

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) 02 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 03 MAR 2021

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 True

Hospital Admission Date (dd MMM yyyy) 03 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 04 MAR 2021

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:13:06

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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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

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

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

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

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

SITE NOTIFIED OF EMERGENT
CHOLECYSTECTOMY
PERFORMED 03 MAR 2021
EVENT REPORTED TO SITE ON
05 MAR 2021. REPORTS SUDDEN
ONSET ABDOMINAL PAIN 02
MAR 2021. PRESENTED TO ER
FOR EVALUATION 03 MAR 2021.
RELEVANT LABS INCLUDE AST
1002 U/L AND ALT 623 U/L ON 03
MAR 2021 AT 0708 AND
RELEVANT DIAGNOSTIC
STUDY INCLUDES
ULTRASOUND RIGHT
ABDOMINAL QUADRANT
IMPRESSION READS AS
FOLLOWS CHOLELITHIASIS
ASSOCIATED MILD
GALLBLADDER WALL
THICKENING COULD BE DUE
TO MILD ACUTE
CHOLECYSTITIS WITH
MURPHY'S SIGN DIFFICULT TO
ASSESS BECAUSE PATIENT
WAS MEDICATED. CLINICAL
CORRELATION SUGGESTED.
ADMITTING DIAGNOSIS
CHOLECYSTITIS.
CHOLECYSTECTOMY 03 MAR
2021. 23 HOUR HOSPITAL STAY.
ALT 850 AST 399 04 MAR 2021
AT 0444. MEDICAL RECORDS
RECEIVED AND REVIEWED 23
MAR 2021.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

AEID

Adverse event

POST PROCEDURE PAIN
(CHOLECYSTECTOMY)

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 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

9 MAR 2021

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 (2)

Data signed: (b) (4) 09 Apr 2021 02:13:06

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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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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

Yes

No

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication ATENOLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 25

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) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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*) 01 JUL 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication DIVALPROEX

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 750

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) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 (3)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 MAR 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication TUMS

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

	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)	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication LANSOPRAZOLE

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration 30

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

	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) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication VITAMIN D3

Prophylaxis Yes
No

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 25

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 (7)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication POST PROCEDURE PAIN
(CHOLECYSTECTOMY)

Dose per administration 1000

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

	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) 04 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication TORADOL

Prophylaxis Yes
No

Indication CHOLECYSTITIS

Dose per administration 15

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)

368 of 2183

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 checked="" 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*) 03 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 03 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication ZOSYN

Prophylaxis Yes
No

Indication CHOLECYSTITIS

Dose per administration 4.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2183

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

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 checked="" 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) 03 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 03 MAR 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2183

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 02:13:06

Generated On: 09 Jun 2021 15:28:53

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
03 MAR 2021	CHOLECYSTECTOMY	Adverse Event	

US3152175

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:28:53

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

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

SAEID	USA-US073-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

SAEID	USA-US073-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/MAR/2021 10:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

SAEID	USA-US073-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

SAEID	USA-US073-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/MAR/2021 08:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

SAEID	USA-US073-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 08:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 17:15:47

Generated On: 09 Jun 2021 15:28:53

SAEID	USA-US073-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/APR/2021 12:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3152175 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

US3152175

Form: Participant Creation

Generated On: 09 Jun 2021 15:28:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'US3152175'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:04:29

US3152175

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Azure Erskine (b) (4)	13 Aug 2020 22:23:39

US3152175

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:04:30

US3152175

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Clinic (Clinic)'	Azure Erskine (b) (4)	13 Aug 2020 22:23:39

US3152175

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'SCRN'	System	13 Aug 2020 22:23:39

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:04:31

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '53'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'YEARS'	System	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '53'	System	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Female (F)'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '1'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Azure Erskine (b) (4)	13 Aug 2020 22:23:52

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '13 Aug 2020'	Azure Erskine (b) (4)	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Aug 2020'	System	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2020'	System	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Amendment 2 (2)'	Azure Erskine (b) (4)	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Azure Erskine (b) (4)	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Azure Erskine (b) (4)	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Azure Erskine (b) (4)	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'No (N)'	Azure Erskine (b) (4)	13 Aug 2020 22:24:06

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 20:04:30

US3152175

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '1'	System	13 Aug 2020 22:24:10

US3152175

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Azure Erskine (b) (4)	13 Aug 2020 22:24:10

US3152175

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:28:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:09:13

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User coded data point as SOC: Cardiac disorders, HLT: Cardiac conduction disorders, PT: Bundle branch block right, LLT: Right bundle branch block - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:31
Data point term sent to Coder	System	14 Aug 2020 17:09:47
User entered 'RIGHT BUNDLE BRANCH BLOCK'	Brandon Essink (b) (4)	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '02 May 2018'	Brandon Essink (b) (4)	14 Aug 2020 17:09:46
	(b) (4)	

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'May 2018'	System	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2018'	System	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:09:46

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
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)	14 Aug 2020 17:11:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:11:32
Data point term sent to Coder	System	14 Aug 2020 17:10:48
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Brandon Essink (b) (4)	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2017'	Brandon Essink (b) (4)	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2017'	System	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2017'	System	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:10:10

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Per MM: Please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:35:22
Query 'Per MM: Please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' answered with 'Stable NCS' (Site from DM).	Azure Erskine (b) (4) (b) (4)	15 Sep 2020 21:08:50
User opened query 'Per MM: Please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 18:04:07
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:12:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:12:28
Data point term sent to Coder	System	14 Aug 2020 17:11:51
User entered 'HYPERTENSION'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 17:11:12
User entered '01 Jul 2020' reason for change: Data Entry Error	Brandon Essink (b) (4)	14 Aug 2020 17:11:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 17:11:02
User entered '01 Jul 2020' (non-conformant).	Brandon Essink (b) (4)	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jul 2020'	System	14 Aug 2020 17:11:12
User entered empty.	System	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2020'	System	14 Aug 2020 17:11:12
User entered empty.	System	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:11:02

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:12:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 17:12:28
Data point term sent to Coder	System	14 Aug 2020 17:11:52
User entered 'ANXIETY'	Brandon Essink (b) (4)	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2015'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2015'	System	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2015'	System	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:11:29

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:13:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:13:25
Data point term sent to Coder	System	14 Aug 2020 17:12:56
User entered 'ENDOMETRIOSIS'	Brandon Essink (b) (4)	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 1990'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2007'	Brandon Essink (b) (4)	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 1990'	System	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '1990'	System	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2007'	System	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2007'	System	14 Aug 2020 17:12:46

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterosalpingo-oophorectomy, LLT: Hysterosalpingo-oophorectomy - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 15:15:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 15:15:22
Data point term sent to Coder	System	14 Aug 2020 17:13:57
User entered 'HYSTERECTOMY AND BILATERAL SALPINOOOPHERECTOMY'	Brandon Essink (b) (4)	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2007'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2007'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2007'	System	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2007'	System	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2007'	System	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2007'	System	14 Aug 2020 17:13:24

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:14:17
Data point term sent to Coder	System	14 Aug 2020 17:13:57
User entered 'APPENDECTOMY'	Brandon Essink (b) (4)	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2007'	Brandon Essink (b) (4)	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 2007'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2007'	System	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2007'	System	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 2007'	System	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '2007'	System	14 Aug 2020 17:13:45

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:16:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:16:30
Data point term sent to Coder	System	14 Aug 2020 17:15:01
User entered 'CARDIAC MURMUR'	Brandon Essink (b) (4)	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'UN UNK 1980'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'Jan 1980'	System	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '1980'	System	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered empty.	System	14 Aug 2020 17:14:02

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '16:15'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered '13 Aug 2020 16:15'	System	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '151.5' cm	Brandon Essink (b) (4)	14 Aug 2020 17:23:05
DataPoint set to visible.	(b) (4) System	13 Aug 2020 22:24:10

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '60.4' kg	Brandon Essink (b) (4)	14 Aug 2020 17:23:05
DataPoint set to visible.	(b) (4) System	13 Aug 2020 22:24:10

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
Amendment Manager: User entered '26.31550'	System	16 Sep 2020 23:56:14
User entered '26.3'	System	14 Aug 2020 17:23:05
DataPoint set to visible.	System	13 Aug 2020 22:24:10

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'kg/m2'	System	14 Aug 2020 17:23:05
DataPoint set to visible.	System	13 Aug 2020 22:24:10

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:46:54
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	12 Sep 2020 13:42:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4) (b) (4)	12 Sep 2020 13:42:23
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	30 Aug 2020 09:33:57
User entered '36.8' C	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:23
User entered 'Oral (Oral)'	Brandon Essink (b) (4)	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:23
User entered '66'	(b) (4)	
	Brandon Essink (b) (4)	14 Aug 2020 17:23:05
	(b) (4)	

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'bpm'	System	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:23
User entered '18'	(b) (4)	
	Brandon Essink (b) (4)	14 Aug 2020 17:23:05
	(b) (4)	

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'breaths/min'	System	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:23
User entered '124'	(b) (4)	
	Brandon Essink (b) (4)	14 Aug 2020 17:23:05
	(b) (4)	

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'mmHg'	System	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:23
User entered '78'	(b) (4)	
	Brandon Essink (b) (4)	14 Aug 2020 17:23:05
	(b) (4)	

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User entered 'mmHg'	System	14 Aug 2020 17:23:05

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07

US3152175

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07

US3152175

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Azure Erskine (b) (4)	13 Aug 2020 22:24:33

US3152175

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 14:33:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 19:44:18
User entered '13 Aug 2020'	Azure Erskine (b) (4) (b) (4)	13 Aug 2020 22:24:33

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '13 Aug 2020'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Surgically sterile (SURGICALLY STERILE)'	Brandon Essink (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'UN UNK 2007'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:28:53

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:25:14

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '1'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '0'	Brandon Essink (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:02:07
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:26:49

US3152175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:27:14

US3152175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Brandon Essink (b) (4)	14 Aug 2020 17:27:14

US3152175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Clinic (Clinic)'	Brandon Essink (b) (4)	14 Aug 2020 17:27:14

US3152175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'VISIT1'	System	14 Aug 2020 17:27:14

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:34:14

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:21:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:21:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 21:34:14
User entered '104056' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:34:14

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:34:14

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

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)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Juliana DeVito (b) (4)	20 Aug 2020 21:26:53
	(b) (4)	

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

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)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:26:53

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:26:53

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:26:53

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:26:53

US3152175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:09:29

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:02:32
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	12 Sep 2020 13:42:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4) (b) (4)	12 Sep 2020 13:42:41
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:51:18
Data hard unlocked.		01 Sep 2020 09:51:11
Data hard locked.		01 Sep 2020 09:51:06
User entered '151.5' cm	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:41
User entered '60.4' kg	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:02:32
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 13:42:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Sep 2020 13:42:41
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:51:18
Data hard unlocked.		01 Sep 2020 09:51:11
Data hard locked.		01 Sep 2020 09:51:06
User entered '151.5' cm	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:41
User entered '60.4' kg	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '16:15'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '13 Aug 2020 16:15'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '36.8' C	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Oral (Oral)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '66'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'bpm'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '18'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'breaths/min'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '124'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '78'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:02:32
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 13:42:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Sep 2020 13:42:41
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:51:18
Data hard unlocked.		01 Sep 2020 09:51:11
Data hard locked.		01 Sep 2020 09:51:06
User entered '151.5' cm	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:41
User entered '60.4' kg	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Ipsita Abalokita (b) (4)	17 Aug 2020 15:04:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN PER PROTOCOL' (Site from System).	Brandon Essink (b) (4)	14 Aug 2020 17:29:49
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 17:29:31
User entered '18:31'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '13 Aug 2020 18:31'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 17:29:55
User entered '36.9' C reason for change: Data Entry Error	Brandon Essink (b) (4)	14 Aug 2020 17:29:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 17:29:31
User entered '36.9' (non-conformant).	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Oral (Oral)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '68'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'bpm'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '12'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'breaths/min'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '128'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '76'	Brandon Essink (b) (4)	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	14 Aug 2020 17:29:31

US3152175

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:51
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:31:04

US3152175

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:42:51
User entered '13 Aug 2020'	Brandon Essink (b) (4)	14 Aug 2020 17:31:04

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Azure Erskine (b) (4)	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Azure Erskine (b) (4)	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Azure Erskine (b) (4)	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Azure Erskine (b) (4)	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '18:00'	Azure Erskine (b) (4)	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '13 Aug 2020 18:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Left Arm (LEFT ARM)'	Azure Erskine (b) (4)	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'ONCE'	System	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 22:25:05

US3152175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 17:33:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 17:33:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Essink (b) (4)	14 Aug 2020 17:33:04
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 17:32:58
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:32:58

US3152175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:32:58

US3152175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '16:40'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:32:58

US3152175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '13 Aug 2020 16:40'	System	14 Aug 2020 17:32:58

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '13 Aug 2020'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '17:17'	Brandon Essink (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '13 Aug 2020 17:17'	System	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	Brandon Essink (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered empty.	System	14 Aug 2020 17:33:52

US3152175

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Brandon Essink (b) (4)	14 Aug 2020 17:34:01

US3152175

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	14 Aug 2020 17:34:01

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:32:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a97cc530-77fc-4d61-b7a2-97ac8f613693'	System	13 Aug 2020 22:32:49
User entered 'Yes (Y)'	System	13 Aug 2020 22:32:49

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:32:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a97cc530-77fc-4d61-b7a2-97ac8f613693'	System	13 Aug 2020 22:32:49
User entered '98.5'	System	13 Aug 2020 22:32:49

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:32:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a97cc530-77fc-4d61-b7a2-97ac8f613693'	System	13 Aug 2020 22:32:49
User entered 'No (N)'	System	13 Aug 2020 22:32:49

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:32:47', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a97cc530-77fc-4d61-b7a2-97ac8f613693'	System	13 Aug 2020 22:32:49
User entered '13 Aug 2020 18:32'	System	13 Aug 2020 22:32:49

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 18:20'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 20:50'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:58:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '683b4c1d-dcd4-44a3-80b9-e55c77b31a1e' User entered 'Yes (Y)'	System	14 Aug 2020 01:59:15
	System	14 Aug 2020 01:59:15

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:58:53', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '683b4c1d-dcd4-44a3-80b9-e55c77b31a1e' User entered '97.8'	System	14 Aug 2020 01:59:15
	System	14 Aug 2020 01:59:15

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:58:59', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '683b4c1d-dcd4-44a3-80b9-e55c77b31a1e' User entered 'No (N)'	System	14 Aug 2020 01:59:15
	System	14 Aug 2020 01:59:15

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:59:12', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '683b4c1d-dcd4-44a3-80b9-e55c77b31a1e' User entered '13 Aug 2020 21:59'	System	14 Aug 2020 01:59:15
	System	14 Aug 2020 01:59:15

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 21:45'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 2'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:08:46', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1890c8c1-babf-4fc1-aeaa-9431d4452d3a'	System	14 Aug 2020 23:09:09
User entered 'Yes (Y)'	System	14 Aug 2020 23:09:09

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:08:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1890c8c1-babf-4fc1-aeaa-9431d4452d3a'	System	14 Aug 2020 23:09:09
User entered '97.6'	System	14 Aug 2020 23:09:09

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1890c8c1-babf-4fc1-aeaa-9431d4452d3a'	System	14 Aug 2020 23:09:09
User entered 'No (N)'	System	14 Aug 2020 23:09:09

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:04', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1890c8c1-babf-4fc1-aeaa-9431d4452d3a' User entered '14 Aug 2020 19:09'	System	14 Aug 2020 23:09:09
	System	14 Aug 2020 23:09:09

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 3'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:14', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a8cdfa84-9183-4de5-a328-d6f10ec18d0d' User entered 'Yes (Y)'	System	15 Aug 2020 16:01:37
	System	15 Aug 2020 16:01:37

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:27', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a8cdfa84-9183-4de5-a328-d6f10ec18d0d' User entered '98.4'	System	15 Aug 2020 16:01:37
	System	15 Aug 2020 16:01:37

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:30', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a8cdfa84-9183-4de5-a328-d6f10ec18d0d'	System	15 Aug 2020 16:01:37
User entered 'No (N)'	System	15 Aug 2020 16:01:37

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a8cdfa84-9183-4de5-a328-d6f10ec18d0d'	System	15 Aug 2020 16:01:37
User entered '15 Aug 2020 12:01'	System	15 Aug 2020 16:01:37

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 4'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:02', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1d0ff04d-8b85-4953-b9f1-f9ee6609ff92'	System	16 Aug 2020 19:51:23
User entered 'Yes (Y)'	System	16 Aug 2020 19:51:23

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1d0ff04d-8b85-4953-b9f1-f9ee6609ff92' User entered '98.5'	System	16 Aug 2020 19:51:23
	System	16 Aug 2020 19:51:23

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1d0ff04d-8b85-4953-b9f1-f9ee6609ff92'	System	16 Aug 2020 19:51:23
User entered 'No (N)'	System	16 Aug 2020 19:51:23

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:20', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1d0ff04d-8b85-4953-b9f1-f9ee6609ff92'	System	16 Aug 2020 19:51:23
User entered '16 Aug 2020 15:51'	System	16 Aug 2020 19:51:23

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 5'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:27:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3085e3cb-adfd-4c90-9329-5616fa70a569' User entered 'Yes (Y)'	System	18 Aug 2020 03:28:06
	System	18 Aug 2020 03:28:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:27:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3085e3cb-adfd-4c90-9329-5616fa70a569' User entered '98.1'	System	18 Aug 2020 03:28:06
	System	18 Aug 2020 03:28:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:01', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3085e3cb-adfd-4c90-9329-5616fa70a569'	System	18 Aug 2020 03:28:06
User entered 'No (N)'	System	18 Aug 2020 03:28:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:03', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3085e3cb-adfd-4c90-9329-5616fa70a569'	System	18 Aug 2020 03:28:06
User entered '17 Aug 2020 23:28'	System	18 Aug 2020 03:28:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 6'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bf5f2aa0-51e4-4b83-b8e8-b540c030cec5'	System	18 Aug 2020 17:17:46
User entered 'Yes (Y)'	System	18 Aug 2020 17:17:46

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bf5f2aa0-51e4-4b83-b8e8-b540c030cec5' User entered '97.8'	System	18 Aug 2020 17:17:46
	System	18 Aug 2020 17:17:46

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:41', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bf5f2aa0-51e4-4b83-b8e8-b540c030cec5'	System	18 Aug 2020 17:17:46
User entered 'No (N)'	System	18 Aug 2020 17:17:46

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:43', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bf5f2aa0-51e4-4b83-b8e8-b540c030cec5'	System	18 Aug 2020 17:17:46
User entered '18 Aug 2020 13:17'	System	18 Aug 2020 17:17:46

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 7'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:30:39', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1263c9cc-969d-4723-83e3-6c2de8803815' User entered 'Yes (Y)'	System	19 Aug 2020 19:31:06
	System	19 Aug 2020 19:31:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:30:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1263c9cc-969d-4723-83e3-6c2de8803815' User entered '98.0'	System	19 Aug 2020 19:31:06
	System	19 Aug 2020 19:31:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:30:59', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1263c9cc-969d-4723-83e3-6c2de8803815' User entered 'No (N)'	System	19 Aug 2020 19:31:06
	System	19 Aug 2020 19:31:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:05', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1263c9cc-969d-4723-83e3-6c2de8803815' User entered '19 Aug 2020 15:31'	System	19 Aug 2020 19:31:06
	System	19 Aug 2020 19:31:06

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:31:18', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1da3ca8e-0040-4a6c-aa3d-63b0b48c47e9'	System	13 Aug 2020 22:31:52
User entered 'None (1)'	System	13 Aug 2020 22:31:52

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:31:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1da3ca8e-0040-4a6c-aa3d-63b0b48c47e9'	System	13 Aug 2020 22:31:52
User entered 'No (N)'	System	13 Aug 2020 22:31:52

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:31:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1da3ca8e-0040-4a6c-aa3d-63b0b48c47e9'	System	13 Aug 2020 22:31:52
User entered 'No (N)'	System	13 Aug 2020 22:31:52

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:31:43', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1da3ca8e-0040-4a6c-aa3d-63b0b48c47e9'	System	13 Aug 2020 22:31:52
User entered 'None (1)'	System	13 Aug 2020 22:31:52

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:31:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1da3ca8e-0040-4a6c-aa3d-63b0b48c47e9' User entered '13 Aug 2020 18:31'	System	13 Aug 2020 22:31:52
	System	13 Aug 2020 22:31:52

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 18:20'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 20:50'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:59:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fdb3453c-50a1-425d-ae92-74b49e14b0df'	System	14 Aug 2020 01:59:56
User entered 'None (1)'	System	14 Aug 2020 01:59:56

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:59:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fdb3453c-50a1-425d-ae92-74b49e14b0df' User entered 'No (N)'	System	14 Aug 2020 01:59:56
	System	14 Aug 2020 01:59:56

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:59:39', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fdb3453c-50a1-425d-ae92-74b49e14b0df' User entered 'No (N)'	System	14 Aug 2020 01:59:56
	System	14 Aug 2020 01:59:56

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:59:49', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fdb3453c-50a1-425d-ae92-74b49e14b0df'	System	14 Aug 2020 01:59:56
User entered 'None (1)'	System	14 Aug 2020 01:59:56

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T21:59:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fdb3453c-50a1-425d-ae92-74b49e14b0df' User entered '13 Aug 2020 21:59'	System	14 Aug 2020 01:59:56
	System	14 Aug 2020 01:59:56

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 21:45'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 2'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:10', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '7c10f889-c58d-4219-9721-da482a0c3a62'	System	14 Aug 2020 23:09:29
User entered 'None (1)'	System	14 Aug 2020 23:09:29

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '7c10f889-c58d-4219-9721-da482a0c3a62'	System	14 Aug 2020 23:09:29
User entered 'No (N)'	System	14 Aug 2020 23:09:29

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:18', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '7c10f889-c58d-4219-9721-da482a0c3a62'	System	14 Aug 2020 23:09:29
User entered 'No (N)'	System	14 Aug 2020 23:09:29

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:23', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '7c10f889-c58d-4219-9721-da482a0c3a62'	System	14 Aug 2020 23:09:29
User entered 'None (1)'	System	14 Aug 2020 23:09:29

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:27', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '7c10f889-c58d-4219-9721-da482a0c3a62'	System	14 Aug 2020 23:09:29
User entered '14 Aug 2020 19:09'	System	14 Aug 2020 23:09:29

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 3'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8f9e796b-53a5-4865-9316-3ad032b3153e'	System	15 Aug 2020 16:02:16
User entered 'None (1)'	System	15 Aug 2020 16:02:16

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:49', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8f9e796b-53a5-4865-9316-3ad032b3153e' User entered 'No (N)'	System	15 Aug 2020 16:02:16
	System	15 Aug 2020 16:02:16

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:01:59', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8f9e796b-53a5-4865-9316-3ad032b3153e' User entered 'No (N)'	System	15 Aug 2020 16:02:16
	System	15 Aug 2020 16:02:16

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:05', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8f9e796b-53a5-4865-9316-3ad032b3153e'	System	15 Aug 2020 16:02:16
User entered 'None (1)'	System	15 Aug 2020 16:02:16

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:11', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8f9e796b-53a5-4865-9316-3ad032b3153e' User entered '15 Aug 2020 12:02'	System	15 Aug 2020 16:02:16
	System	15 Aug 2020 16:02:16

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 4'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:27', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3538e0e7-6ea0-4fe9-9077-7e4daaa5246f' User entered 'None (1)'	System	16 Aug 2020 19:51:53
	System	16 Aug 2020 19:51:53

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3538e0e7-6ea0-4fe9-9077-7e4daaa5246f' User entered 'No (N)'	System	16 Aug 2020 19:51:53
	System	16 Aug 2020 19:51:53

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3538e0e7-6ea0-4fe9-9077-7e4daaa5246f' User entered 'No (N)'	System	16 Aug 2020 19:51:53
	System	16 Aug 2020 19:51:53

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:48', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3538e0e7-6ea0-4fe9-9077-7e4daaa5246f' User entered 'None (1)'	System	16 Aug 2020 19:51:53
	System	16 Aug 2020 19:51:53

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:51', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3538e0e7-6ea0-4fe9-9077-7e4daaa5246f' User entered '16 Aug 2020 15:51'	System	16 Aug 2020 19:51:53
	System	16 Aug 2020 19:51:53

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 5'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4116924a-a31f-4520-8e50-0b2abc82b63a'	System	18 Aug 2020 03:28:22
User entered 'None (1)'	System	18 Aug 2020 03:28:22

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:10', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4116924a-a31f-4520-8e50-0b2abc82b63a' User entered 'No (N)'	System	18 Aug 2020 03:28:22
	System	18 Aug 2020 03:28:22

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4116924a-a31f-4520-8e50-0b2abc82b63a' User entered 'No (N)'	System	18 Aug 2020 03:28:22
	System	18 Aug 2020 03:28:22

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4116924a-a31f-4520-8e50-0b2abc82b63a'	System	18 Aug 2020 03:28:22
User entered 'None (1)'	System	18 Aug 2020 03:28:22

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:18', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4116924a-a31f-4520-8e50-0b2abc82b63a' User entered '17 Aug 2020 23:28'	System	18 Aug 2020 03:28:22
	System	18 Aug 2020 03:28:22

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 6'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:48', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4023cf62-eeb4-467f-a621-138012a4b657'	System	18 Aug 2020 17:18:05
User entered 'None (1)'	System	18 Aug 2020 17:18:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:51', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4023cf62-eeb4-467f-a621-138012a4b657'	System	18 Aug 2020 17:18:05
User entered 'No (N)'	System	18 Aug 2020 17:18:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:53', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4023cf62-eeb4-467f-a621-138012a4b657'	System	18 Aug 2020 17:18:05
User entered 'No (N)'	System	18 Aug 2020 17:18:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:17:59', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4023cf62-eeb4-467f-a621-138012a4b657'	System	18 Aug 2020 17:18:05
User entered 'None (1)'	System	18 Aug 2020 17:18:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:02', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4023cf62-eeb4-467f-a621-138012a4b657'	System	18 Aug 2020 17:18:05
User entered '18 Aug 2020 13:18'	System	18 Aug 2020 17:18:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 7'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:11', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '29ee39b5-7dd3-4e4f-be0a-d3136fbea34b'	System	19 Aug 2020 19:31:31
User entered 'None (1)'	System	19 Aug 2020 19:31:31

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:16', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '29ee39b5-7dd3-4e4f-be0a-d3136fbea34b'	System	19 Aug 2020 19:31:31
User entered 'No (N)'	System	19 Aug 2020 19:31:31

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:23', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '29ee39b5-7dd3-4e4f-be0a-d3136fbea34b'	System	19 Aug 2020 19:31:31
User entered 'No (N)'	System	19 Aug 2020 19:31:31

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:25', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '29ee39b5-7dd3-4e4f-be0a-d3136fbea34b'	System	19 Aug 2020 19:31:31
User entered 'None (1)'	System	19 Aug 2020 19:31:31

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:28', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '29ee39b5-7dd3-4e4f-be0a-d3136fbea34b' User entered '19 Aug 2020 15:31'	System	19 Aug 2020 19:31:31
	System	19 Aug 2020 19:31:31

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:33:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'None (0)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:33:57', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'None (0)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:34:01', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'None (0)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:34:04', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'None (0)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:34:06', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'None (0)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:34:08', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'None (0)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:34:12', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered 'No (N)'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T18:34:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '32747952-8306-4334-9698-1528c518e9a4'	System	13 Aug 2020 22:34:17
User entered '13 Aug 2020 18:34'	System	13 Aug 2020 22:34:17

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 18:20'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 20:50'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:03', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered 'None (0)'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:10', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered 'None (0)'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered 'None (0)'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:20', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered 'None (0)'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:22', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered 'None (0)'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered 'None (0)'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31'	System	14 Aug 2020 02:00:38
User entered 'No (N)'	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-13T22:00:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'dcaff04d-43ea-47e0-bebe-606e81392f31' User entered '13 Aug 2020 22:00'	System	14 Aug 2020 02:00:38
	System	14 Aug 2020 02:00:38

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Aug 2020 21:45'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 2'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:33', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered 'None (0)'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:44', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered 'No interference with activity (1)'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:47', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered 'None (0)'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2' User entered 'None (0)'	System	14 Aug 2020 23:10:05
	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered 'None (0)'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered 'None (0)'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:09:59', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered 'No (N)'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-14T19:10:01', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3f52c0f4-bc6d-4499-b08b-5845ee2e8dd2'	System	14 Aug 2020 23:10:05
User entered '14 Aug 2020 19:10'	System	14 Aug 2020 23:10:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 3'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:16', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered 'None (0)'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca'	System	15 Aug 2020 16:02:45
User entered 'No interference with activity (1)'	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:25', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered 'None (0)'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:27', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered 'None (0)'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered 'None (0)'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:33', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered 'None (0)'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:39', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered 'No (N)'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-15T12:02:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5649c352-d46e-42fb-b5f3-52432d717bca' User entered '15 Aug 2020 12:02'	System	15 Aug 2020 16:02:45
	System	15 Aug 2020 16:02:45

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 4'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:51:57', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92' User entered 'None (0)'	System	16 Aug 2020 19:52:29
	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:03', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92'	System	16 Aug 2020 19:52:29
User entered 'No interference with activity (1)'	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92' User entered 'None (0)'	System	16 Aug 2020 19:52:29
	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:11', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92' User entered 'None (0)'	System	16 Aug 2020 19:52:29
	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:14', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92' User entered 'None (0)'	System	16 Aug 2020 19:52:29
	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:17', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92' User entered 'None (0)'	System	16 Aug 2020 19:52:29
	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92' User entered 'No (N)'	System	16 Aug 2020 19:52:29
	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-16T15:52:26', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '595f1e1d-271a-4612-b2bb-41ff88ebbe92'	System	16 Aug 2020 19:52:29
User entered '16 Aug 2020 15:52'	System	16 Aug 2020 19:52:29

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 5'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:22', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'None (0)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'None (0)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:26', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'None (0)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:27', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'None (0)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:29', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'None (0)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:30', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'None (0)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:33', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered 'No (N)'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-17T23:28:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '23563fed-0d19-44a5-ab72-2f7b2a96c0e8' User entered '17 Aug 2020 23:28'	System	18 Aug 2020 03:28:40
	System	18 Aug 2020 03:28:40

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 6'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'None (0)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:16', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'None (0)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'None (0)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'None (0)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'None (0)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:26', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'None (0)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered 'No (N)'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-18T13:18:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'b99edba9-3ca2-407c-95cd-34e0bd036a00' User entered '18 Aug 2020 13:18'	System	18 Aug 2020 17:18:41
	System	18 Aug 2020 17:18:41

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 7'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:32', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9'	System	19 Aug 2020 19:31:55
User entered 'None (0)'	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9'	System	19 Aug 2020 19:31:55
User entered 'None (0)'	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:38', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9'	System	19 Aug 2020 19:31:55
User entered 'None (0)'	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9' User entered 'None (0)'	System	19 Aug 2020 19:31:55
	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:44', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9'	System	19 Aug 2020 19:31:55
User entered 'None (0)'	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:46', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9'	System	19 Aug 2020 19:31:55
User entered 'None (0)'	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9'	System	19 Aug 2020 19:31:55
User entered 'No (N)'	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-08-19T15:31:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'fe126ac0-3677-48fc-940b-e388fe0fd3e9' User entered '19 Aug 2020 15:31'	System	19 Aug 2020 19:31:55
	System	19 Aug 2020 19:31:55

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:25:05

US3152175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:35:29

US3152175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '20 Aug 2020'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:35:29

US3152175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Contact Made (CONTACT MADE)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:35:29

US3152175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:35:29

US3152175

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:35:37

US3152175

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'I'	System	20 Aug 2020 21:35:37

US3152175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Jemario Blackwell (b) (4) (b) (4)	28 Aug 2020 14:42:16

US3152175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '28 Aug 2020'	Jemario Blackwell (b) (4) (b) (4)	28 Aug 2020 14:42:16

US3152175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	28 Aug 2020 14:42:16

US3152175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	28 Aug 2020 14:42:16

US3152175

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Jemario Blackwell (b) (4) (b) (4)	28 Aug 2020 14:42:20

US3152175

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	28 Aug 2020 14:42:20

US3152175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Devan Myers (b) (4)	11 Sep 2020 19:55:26

US3152175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '4 Sep 2020'	Devan Myers (b) (4)	11 Sep 2020 19:55:26

US3152175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	11 Sep 2020 19:55:26

US3152175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	Devan Myers (b) (4)	11 Sep 2020 19:55:26

US3152175

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	Devan Myers (b) (4)	11 Sep 2020 19:55:42

US3152175

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	11 Sep 2020 19:55:42

US3152175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:44:18

US3152175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 19:44:18

US3152175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Sep 2020 19:44:18

US3152175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'VISIT2'	System	12 Sep 2020 19:44:18

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Pre-Dose (PREDOSE)'		12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '14:55'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '11 Sep 2020 14:55'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '37.1' C	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '65'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'bpm'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '15'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'breaths/min'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '121'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '76'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Post-Dose (POSTDOSE)'		12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '16:23'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '11 Sep 2020 16:23'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '36.5' C	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '58'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'bpm'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '15'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'breaths/min'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '122'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '78'	(b) (4), (b) (6)	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	12 Sep 2020 19:46:59

US3152175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:47:11

US3152175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 19:47:11

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	Devan Myers (b) (4)	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Devan Myers (b) (4)	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	Devan Myers (b) (4)	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '11 Sep 2020'	Devan Myers (b) (4)	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '15:53'	Devan Myers (b) (4)	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '11 Sep 2020 15:53'	System	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'ONCE'	System	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 19:56:39

US3152175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:48:14

US3152175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 19:48:14

US3152175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '15:02'	(b) (4), (b) (6)	12 Sep 2020 19:48:14

US3152175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '11 Sep 2020 15:02'	System	12 Sep 2020 19:48:14

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	12 Sep 2020 19:48:44
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	12 Sep 2020 19:48:44
User entered '11 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	12 Sep 2020 19:48:44
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	12 Sep 2020 19:48:33
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '15:22'	(b) (4), (b) (6)	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '11 Sep 2020 15:22'	System	12 Sep 2020 19:48:44
User entered empty.	System	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	(b) (4), (b) (6)	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered empty.	System	12 Sep 2020 19:48:33

US3152175

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:48:52

US3152175

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	12 Sep 2020 19:48:52

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:23:26', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5fb70401-0549-4fc9-b3e4-643e734b9c03'	System	11 Sep 2020 20:23:48
User entered 'Yes (Y)'	System	11 Sep 2020 20:23:48

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:23:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5fb70401-0549-4fc9-b3e4-643e734b9c03'	System	11 Sep 2020 20:23:48
User entered '97.7'	System	11 Sep 2020 20:23:48

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:23:41', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5fb70401-0549-4fc9-b3e4-643e734b9c03'	System	11 Sep 2020 20:23:48
User entered 'No (N)'	System	11 Sep 2020 20:23:48

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:23:45', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '5fb70401-0549-4fc9-b3e4-643e734b9c03'	System	11 Sep 2020 20:23:48
User entered '11 Sep 2020 16:23'	System	11 Sep 2020 20:23:48

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 16:13'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 18:43'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:43:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e6c5ea17-4307-40f7-a726-6dfa5308424a'	System	11 Sep 2020 23:44:06
User entered 'Yes (Y)'	System	11 Sep 2020 23:44:06

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:43:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e6c5ea17-4307-40f7-a726-6dfa5308424a' User entered '98.7'	System	11 Sep 2020 23:44:06
	System	11 Sep 2020 23:44:06

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:43:58', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e6c5ea17-4307-40f7-a726-6dfa5308424a'	System	11 Sep 2020 23:44:06
User entered 'No (N)'	System	11 Sep 2020 23:44:06

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:02', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e6c5ea17-4307-40f7-a726-6dfa5308424a'	System	11 Sep 2020 23:44:06
User entered '11 Sep 2020 19:44'	System	11 Sep 2020 23:44:06

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 19:38'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 2'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6cfed19f-4cd6-4c86-8aa8-8ca8d16425e2'	System	13 Sep 2020 00:25:38
User entered 'Yes (Y)'	System	13 Sep 2020 00:25:38

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:25', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6cfed19f-4cd6-4c86-8aa8-8ca8d16425e2' User entered '98.0'	System	13 Sep 2020 00:25:38
	System	13 Sep 2020 00:25:38

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6cfed19f-4cd6-4c86-8aa8-8ca8d16425e2'	System	13 Sep 2020 00:25:38
User entered 'No (N)'	System	13 Sep 2020 00:25:38

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6cfed19f-4cd6-4c86-8aa8-8ca8d16425e2'	System	13 Sep 2020 00:25:38
User entered '12 Sep 2020 20:25'	System	13 Sep 2020 00:25:38

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 3'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:49:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f7a84221-1e27-4716-a1e2-43b456e55e12'	System	13 Sep 2020 19:50:15
User entered 'Yes (Y)'	System	13 Sep 2020 19:50:15

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:49:57', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f7a84221-1e27-4716-a1e2-43b456e55e12' User entered '98.3'	System	13 Sep 2020 19:50:15
	System	13 Sep 2020 19:50:15

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f7a84221-1e27-4716-a1e2-43b456e55e12'	System	13 Sep 2020 19:50:15
User entered 'No (N)'	System	13 Sep 2020 19:50:15

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:05', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f7a84221-1e27-4716-a1e2-43b456e55e12'	System	13 Sep 2020 19:50:15
User entered '13 Sep 2020 15:50'	System	13 Sep 2020 19:50:15

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 4'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:09:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '39863455-4c1c-4b1c-a44a-1651e80675b4'	System	15 Sep 2020 00:10:14
User entered 'Yes (Y)'	System	15 Sep 2020 00:10:14

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '39863455-4c1c-4b1c-a44a-1651e80675b4' User entered '98.7'	System	15 Sep 2020 00:10:14
	System	15 Sep 2020 00:10:14

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:03', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '39863455-4c1c-4b1c-a44a-1651e80675b4'	System	15 Sep 2020 00:10:14
User entered 'No (N)'	System	15 Sep 2020 00:10:14

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:06', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '39863455-4c1c-4b1c-a44a-1651e80675b4'	System	15 Sep 2020 00:10:14
User entered '14 Sep 2020 20:10'	System	15 Sep 2020 00:10:14

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 5'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:39', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f8f069e9-f893-4509-bbc4-610118f12565'	System	15 Sep 2020 16:52:51
User entered 'Yes (Y)'	System	15 Sep 2020 16:52:51

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:44', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f8f069e9-f893-4509-bbc4-610118f12565'	System	15 Sep 2020 16:52:51
User entered '97.9'	System	15 Sep 2020 16:52:51

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:46', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f8f069e9-f893-4509-bbc4-610118f12565'	System	15 Sep 2020 16:52:51
User entered 'No (N)'	System	15 Sep 2020 16:52:51

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:49', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f8f069e9-f893-4509-bbc4-610118f12565'	System	15 Sep 2020 16:52:51
User entered '15 Sep 2020 12:52'	System	15 Sep 2020 16:52:51

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 6'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:27:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3897fbf8-f270-4ec0-a354-390e70953c59'	System	16 Sep 2020 16:27:53
User entered 'Yes (Y)'	System	16 Sep 2020 16:27:53

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:27:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3897fbf8-f270-4ec0-a354-390e70953c59'	System	16 Sep 2020 16:27:53
User entered '97.8'	System	16 Sep 2020 16:27:53

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:27:46', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3897fbf8-f270-4ec0-a354-390e70953c59'	System	16 Sep 2020 16:27:53
User entered 'No (N)'	System	16 Sep 2020 16:27:53

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:27:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3897fbf8-f270-4ec0-a354-390e70953c59'	System	16 Sep 2020 16:27:53
User entered '16 Sep 2020 12:27'	System	16 Sep 2020 16:27:53

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 7'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:20', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6aae6ff-5d45-4234-86c6-e5345c6a142a' User entered 'Yes (Y)'	System	17 Sep 2020 20:51:32
	System	17 Sep 2020 20:51:32

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:25', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6aae6ff-5d45-4234-86c6-e5345c6a142a' User entered '97.4'	System	17 Sep 2020 20:51:32
	System	17 Sep 2020 20:51:32

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:28', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6aae6ff-5d45-4234-86c6-e5345c6a142a'	System	17 Sep 2020 20:51:32
User entered 'No (N)'	System	17 Sep 2020 20:51:32

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:30', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6aae6ff-5d45-4234-86c6-e5345c6a142a'	System	17 Sep 2020 20:51:32
User entered '17 Sep 2020 16:51'	System	17 Sep 2020 20:51:32

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:23:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '98f83d2b-9d61-45f7-85b4-7c9a96d1a651'	System	11 Sep 2020 20:24:12
User entered 'None (1)'	System	11 Sep 2020 20:24:12

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:23:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '98f83d2b-9d61-45f7-85b4-7c9a96d1a651'	System	11 Sep 2020 20:24:12
User entered 'No (N)'	System	11 Sep 2020 20:24:12

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:01', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '98f83d2b-9d61-45f7-85b4-7c9a96d1a651'	System	11 Sep 2020 20:24:12
User entered 'No (N)'	System	11 Sep 2020 20:24:12

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:06', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '98f83d2b-9d61-45f7-85b4-7c9a96d1a651'	System	11 Sep 2020 20:24:12
User entered 'None (1)'	System	11 Sep 2020 20:24:12

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:08', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '98f83d2b-9d61-45f7-85b4-7c9a96d1a651'	System	11 Sep 2020 20:24:12
User entered '11 Sep 2020 16:24'	System	11 Sep 2020 20:24:12

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 16:13'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 18:43'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:08', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '051a59c7-d641-47b0-be56-4083302a1687'	System	11 Sep 2020 23:44:30
User entered 'None (1)'	System	11 Sep 2020 23:44:30

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '051a59c7-d641-47b0-be56-4083302a1687'	System	11 Sep 2020 23:44:30
User entered 'No (N)'	System	11 Sep 2020 23:44:30

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:17', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '051a59c7-d641-47b0-be56-4083302a1687'	System	11 Sep 2020 23:44:30
User entered 'No (N)'	System	11 Sep 2020 23:44:30

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:22', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '051a59c7-d641-47b0-be56-4083302a1687'	System	11 Sep 2020 23:44:30
User entered 'None (1)'	System	11 Sep 2020 23:44:30

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '051a59c7-d641-47b0-be56-4083302a1687'	System	11 Sep 2020 23:44:30
User entered '11 Sep 2020 19:44'	System	11 Sep 2020 23:44:30

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 19:38'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 2'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:47', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '783be037-5d3c-4670-800a-4d49f36fa8d5'	System	13 Sep 2020 00:26:04
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 00:26:04

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:49', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '783be037-5d3c-4670-800a-4d49f36fa8d5'	System	13 Sep 2020 00:26:04
User entered 'No (N)'	System	13 Sep 2020 00:26:04

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '783be037-5d3c-4670-800a-4d49f36fa8d5'	System	13 Sep 2020 00:26:04
User entered 'No (N)'	System	13 Sep 2020 00:26:04

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:25:59', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '783be037-5d3c-4670-800a-4d49f36fa8d5'	System	13 Sep 2020 00:26:04
User entered 'None (1)'	System	13 Sep 2020 00:26:04

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:02', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '783be037-5d3c-4670-800a-4d49f36fa8d5'	System	13 Sep 2020 00:26:04
User entered '12 Sep 2020 20:26'	System	13 Sep 2020 00:26:04

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 3'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6630a723-7de9-4aef-a227-e55600326ef1'	System	13 Sep 2020 19:50:53
User entered 'None (1)'	System	13 Sep 2020 19:50:53

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6630a723-7de9-4aef-a227-e55600326ef1'	System	13 Sep 2020 19:50:53
User entered 'No (N)'	System	13 Sep 2020 19:50:53

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:18', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6630a723-7de9-4aef-a227-e55600326ef1'	System	13 Sep 2020 19:50:53
User entered 'No (N)'	System	13 Sep 2020 19:50:53

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6630a723-7de9-4aef-a227-e55600326ef1'	System	13 Sep 2020 19:50:53
User entered 'None (1)'	System	13 Sep 2020 19:50:53

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:39', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '6630a723-7de9-4aef-a227-e55600326ef1' User entered '13 Sep 2020 15:50'	System	13 Sep 2020 19:50:53
	System	13 Sep 2020 19:50:53

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 4'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f1a2b3d7-299e-4d04-81c8-07805e8e998a' User entered 'None (1)'	System	15 Sep 2020 00:10:28
	System	15 Sep 2020 00:10:28

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:14', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f1a2b3d7-299e-4d04-81c8-07805e8e998a' User entered 'No (N)'	System	15 Sep 2020 00:10:28
	System	15 Sep 2020 00:10:28

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:16', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f1a2b3d7-299e-4d04-81c8-07805e8e998a' User entered 'No (N)'	System	15 Sep 2020 00:10:28
	System	15 Sep 2020 00:10:28

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:22', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f1a2b3d7-299e-4d04-81c8-07805e8e998a' User entered 'None (1)'	System	15 Sep 2020 00:10:28
	System	15 Sep 2020 00:10:28

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f1a2b3d7-299e-4d04-81c8-07805e8e998a' User entered '14 Sep 2020 20:10'	System	15 Sep 2020 00:10:28
	System	15 Sep 2020 00:10:28

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 5'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e61de5b3-61e3-42c7-91fd-f24874c38369'	System	15 Sep 2020 16:53:06
User entered 'None (1)'	System	15 Sep 2020 16:53:06

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e61de5b3-61e3-42c7-91fd-f24874c38369'	System	15 Sep 2020 16:53:06
User entered 'No (N)'	System	15 Sep 2020 16:53:06

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e61de5b3-61e3-42c7-91fd-f24874c38369'	System	15 Sep 2020 16:53:06
User entered 'No (N)'	System	15 Sep 2020 16:53:06

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:52:57', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e61de5b3-61e3-42c7-91fd-f24874c38369'	System	15 Sep 2020 16:53:06
User entered 'None (1)'	System	15 Sep 2020 16:53:06

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e61de5b3-61e3-42c7-91fd-f24874c38369' User entered '15 Sep 2020 12:53'	System	15 Sep 2020 16:53:06
	System	15 Sep 2020 16:53:06

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 6'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:27:53', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '93a97b87-7828-4247-b0cd-24d864e65660'	System	16 Sep 2020 16:28:08
User entered 'None (1)'	System	16 Sep 2020 16:28:08

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:27:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '93a97b87-7828-4247-b0cd-24d864e65660'	System	16 Sep 2020 16:28:08
User entered 'No (N)'	System	16 Sep 2020 16:28:08

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '93a97b87-7828-4247-b0cd-24d864e65660'	System	16 Sep 2020 16:28:08
User entered 'No (N)'	System	16 Sep 2020 16:28:08

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:02', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '93a97b87-7828-4247-b0cd-24d864e65660'	System	16 Sep 2020 16:28:08
User entered 'None (1)'	System	16 Sep 2020 16:28:08

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:05', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '93a97b87-7828-4247-b0cd-24d864e65660'	System	16 Sep 2020 16:28:08
User entered '16 Sep 2020 12:28'	System	16 Sep 2020 16:28:08

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 7'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:33', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0f98af9c-8db5-42c6-86d1-8acf137eb2ed'	System	17 Sep 2020 20:51:43
User entered 'None (1)'	System	17 Sep 2020 20:51:43

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0f98af9c-8db5-42c6-86d1-8acf137eb2ed'	System	17 Sep 2020 20:51:43
User entered 'No (N)'	System	17 Sep 2020 20:51:43

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0f98af9c-8db5-42c6-86d1-8acf137eb2ed' User entered 'No (N)'	System	17 Sep 2020 20:51:43
	System	17 Sep 2020 20:51:43

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:38', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0f98af9c-8db5-42c6-86d1-8acf137eb2ed'	System	17 Sep 2020 20:51:43
User entered 'None (1)'	System	17 Sep 2020 20:51:43

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:41', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0f98af9c-8db5-42c6-86d1-8acf137eb2ed' User entered '17 Sep 2020 16:51'	System	17 Sep 2020 20:51:43
	System	17 Sep 2020 20:51:43

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'None (0)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'None (0)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:17', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'None (0)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'None (0)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:20', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'None (0)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:22', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'None (0)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:26', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered 'No (N)'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T16:24:28', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '88b1a116-4eba-4d18-be71-e352ae1f236f' User entered '11 Sep 2020 16:24'	System	11 Sep 2020 20:24:31
	System	11 Sep 2020 20:24:31

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 16:13'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 18:43'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:29', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'None (0)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'None (0)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:33', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'None (0)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:34', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'None (0)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'None (0)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'None (0)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered 'No (N)'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-11T19:44:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '11a37e19-8c0c-46d6-9749-9558b92715fb' User entered '11 Sep 2020 19:44'	System	11 Sep 2020 23:44:44
	System	11 Sep 2020 23:44:44

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '11 Sep 2020 19:38'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 2'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:06', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'None (0)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'None (0)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:11', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'None (0)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'None (0)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'None (0)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'None (0)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered 'No (N)'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-12T20:26:27', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a4b25f6-5fd5-49b9-9c9d-65f810174fd7'	System	13 Sep 2020 00:26:33
User entered '12 Sep 2020 20:26'	System	13 Sep 2020 00:26:33

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 3'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:44', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered 'None (0)'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:46', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered 'None (0)'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:48', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered 'None (0)'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered 'None (0)'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered 'None (0)'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:50:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered 'None (0)'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:51:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e'	System	13 Sep 2020 19:51:14
User entered 'No (N)'	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-13T15:51:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0d1b234b-9d79-4ea9-b911-8749b6b9565e' User entered '13 Sep 2020 15:51'	System	13 Sep 2020 19:51:14
	System	13 Sep 2020 19:51:14

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 4'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:28', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0' User entered 'None (0)'	System	15 Sep 2020 00:10:48
	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0' User entered 'None (0)'	System	15 Sep 2020 00:10:48
	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:34', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0'	System	15 Sep 2020 00:10:48
User entered 'None (0)'	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0' User entered 'None (0)'	System	15 Sep 2020 00:10:48
	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:37', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0' User entered 'None (0)'	System	15 Sep 2020 00:10:48
	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:38', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0' User entered 'None (0)'	System	15 Sep 2020 00:10:48
	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:41', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0'	System	15 Sep 2020 00:10:48
User entered 'No (N)'	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-14T20:10:43', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e5cd60f9-e65f-436b-a184-77f4fe240ab0'	System	15 Sep 2020 00:10:48
User entered '14 Sep 2020 20:10'	System	15 Sep 2020 00:10:48

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 5'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:02', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered 'None (0)'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:04', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered 'None (0)'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:05', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered 'None (0)'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered 'None (0)'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:08', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered 'None (0)'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:10', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68' User entered 'None (0)'	System	15 Sep 2020 16:53:16
	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:12', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered 'No (N)'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-15T12:53:14', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd1d9a0cb-19c0-4a6b-8e56-2f70f21e5e68'	System	15 Sep 2020 16:53:16
User entered '15 Sep 2020 12:53'	System	15 Sep 2020 16:53:16

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 6'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'None (0)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:10', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'None (0)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:12', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'None (0)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'None (0)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'None (0)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:16', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'None (0)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b' User entered 'No (N)'	System	16 Sep 2020 16:28:26
	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-16T12:28:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '15508a07-bacf-4565-85bf-f8b8630ab26b'	System	16 Sep 2020 16:28:26
User entered '16 Sep 2020 12:28'	System	16 Sep 2020 16:28:26

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	11 Sep 2020 19:56:39
User entered 'Day 7'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:44', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d'	System	17 Sep 2020 20:51:58
User entered 'None (0)'	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:45', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d' User entered 'None (0)'	System	17 Sep 2020 20:51:58
	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:46', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d' User entered 'None (0)'	System	17 Sep 2020 20:51:58
	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:48', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d' User entered 'None (0)'	System	17 Sep 2020 20:51:58
	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d' User entered 'None (0)'	System	17 Sep 2020 20:51:58
	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:51', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d' User entered 'None (0)'	System	17 Sep 2020 20:51:58
	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

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)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:53', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d'	System	17 Sep 2020 20:51:58
User entered 'No (N)'	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-09-17T16:51:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '10e1129e-162c-42cb-9f5a-88dad2d7e03d' User entered '17 Sep 2020 16:51'	System	17 Sep 2020 20:51:58
	System	17 Sep 2020 20:51:58

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:56:39

US3152175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:56:39

US3152175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:31:41

US3152175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '21 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 18:31:41

US3152175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 18:31:41

US3152175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:31:41

US3152175

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:31:46

US3152175

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	08 Oct 2020 18:31:46

US3152175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:32:11

US3152175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered '25 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 18:32:11

US3152175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 18:32:11

US3152175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:32:11

US3152175

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:32:17

US3152175

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	08 Oct 2020 18:32:17

US3152175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:43:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:32:32

US3152175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:43:24
User entered '02 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 18:32:32

US3152175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:43:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 18:32:32

US3152175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:43:24
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:32:32

US3152175

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:43:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:32:38

US3152175

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	08 Oct 2020 18:32:38

US3152175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:33:10

US3152175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 18:33:10

US3152175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 18:33:10

US3152175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'VISIT3'	System	08 Oct 2020 18:33:10

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '14:00'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '08 Oct 2020 14:00'	System	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '37.3' C	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '62'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'bpm'	System	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '14'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'breaths/min'	System	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '115'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '71'	(b) (4), (b) (6)	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered 'mmHg'	System	08 Oct 2020 18:33:50

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05

US3152175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05

US3152175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 18:33:55

US3152175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:33:55

US3152175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:34:14

US3152175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 18:34:14

US3152175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered '14:17'	(b) (4), (b) (6)	08 Oct 2020 18:34:14

US3152175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '08 Oct 2020 14:17'	System	08 Oct 2020 18:34:14

US3152175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 18:34:18

US3152175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	08 Oct 2020 18:34:18

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 64'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-13T18:45:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6e9a895-c045-4822-a985-5423cb5d050c'	System	13 Oct 2020 22:45:25
User entered 'No (N)'	System	13 Oct 2020 22:45:25

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-13T18:45:12', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6e9a895-c045-4822-a985-5423cb5d050c'	System	13 Oct 2020 22:45:25
User entered 'No (N)'	System	13 Oct 2020 22:45:25

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-13T18:45:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a6e9a895-c045-4822-a985-5423cb5d050c' User entered '13 Oct 2020 18:45:21'	System	13 Oct 2020 22:45:25
	System	13 Oct 2020 22:45:25

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 71'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-20T05:45:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '62f108b2-cbd2-4885-8162-d7bec6380e72'	System	20 Oct 2020 09:45:45
User entered 'No (N)'	System	20 Oct 2020 09:45:45

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-20T05:45:34', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '62f108b2-cbd2-4885-8162-d7bec6380e72'	System	20 Oct 2020 09:45:45
User entered 'No (N)'	System	20 Oct 2020 09:45:45

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-20T05:45:41', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '62f108b2-cbd2-4885-8162-d7bec6380e72' User entered '20 Oct 2020 05:45:41'	System	20 Oct 2020 09:45:45
	System	20 Oct 2020 09:45:45

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 78'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-27T13:56:58', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3a923f24-14ce-46a4-b31d-fb7014c18ec8'	System	27 Oct 2020 23:29:27
User entered 'No (N)'	System	27 Oct 2020 23:29:27

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-27T13:57:03', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3a923f24-14ce-46a4-b31d-fb7014c18ec8'	System	27 Oct 2020 23:29:27
User entered 'No (N)'	System	27 Oct 2020 23:29:27

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-10-27T13:57:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3a923f24-14ce-46a4-b31d-fb7014c18ec8' User entered '27 Oct 2020 13:57:09'	System	27 Oct 2020 23:29:27
	System	27 Oct 2020 23:29:27

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 92'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-11T00:06:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bc3dcfa0-75d2-4807-8037-2d0331ccbd24'	System	11 Nov 2020 05:06:59
User entered 'No (N)'	System	11 Nov 2020 05:06:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-11T00:06:48', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bc3dcfa0-75d2-4807-8037-2d0331ccbd24'	System	11 Nov 2020 05:06:59
User entered 'No (N)'	System	11 Nov 2020 05:06:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-11T00:06:56', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'bc3dcfa0-75d2-4807-8037-2d0331ccbd24'	System	11 Nov 2020 05:06:59
User entered '11 Nov 2020 00:06:56'	System	11 Nov 2020 05:06:59

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered 'Day 99'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-17T16:11:45', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a349608-2f3c-48cd-a48e-5047d74a601e'	System	17 Nov 2020 21:12:00
User entered 'No (N)'	System	17 Nov 2020 21:12:00

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-17T16:11:53', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a349608-2f3c-48cd-a48e-5047d74a601e' User entered 'No (N)'	System	17 Nov 2020 21:12:00
	System	17 Nov 2020 21:12:00

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-17T16:11:57', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '8a349608-2f3c-48cd-a48e-5047d74a601e' User entered '17 Nov 2020 16:11:57'	System	17 Nov 2020 21:12:00
	System	17 Nov 2020 21:12:00

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 22:25:05

US3152175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:37:13
Data entry locked.	System	13 Aug 2020 22:25:05
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 22:25:05

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-22T06:27:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd7cebce9-bb31-4db7-9644-832c087f7048'	System	22 Nov 2020 11:27:34
User entered 'No (N)'	System	22 Nov 2020 11:27:34

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-22T06:27:26', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd7cebce9-bb31-4db7-9644-832c087f7048'	System	22 Nov 2020 11:27:34
User entered 'No (N)'	System	22 Nov 2020 11:27:34

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-22T06:27:30', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd7cebce9-bb31-4db7-9644-832c087f7048' User entered '22 Nov 2020 06:27:30'	System	22 Nov 2020 11:27:34
	System	22 Nov 2020 11:27:34

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-28T20:04:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '717993f7-a303-4f8a-88e8-01acf5426077'	System	29 Nov 2020 01:04:43
User entered 'No (N)'	System	29 Nov 2020 01:04:43

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-28T20:04:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '717993f7-a303-4f8a-88e8-01acf5426077'	System	29 Nov 2020 01:04:43
User entered 'No (N)'	System	29 Nov 2020 01:04:43

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-11-28T20:04:40', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '717993f7-a303-4f8a-88e8-01acf5426077'	System	29 Nov 2020 01:04:43
User entered '28 Nov 2020 20:04:40'	System	29 Nov 2020 01:04:43

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-07T17:06:19', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'c8894cd4-1d2a-4f8a-8aa8-86f24e2b92fd'	System	07 Dec 2020 22:06:36
User entered 'No (N)'	System	07 Dec 2020 22:06:36

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-07T17:06:29', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'c8894cd4-1d2a-4f8a-8aa8-86f24e2b92fd'	System	07 Dec 2020 22:06:36
User entered 'No (N)'	System	07 Dec 2020 22:06:36

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-07T17:06:33', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'c8894cd4-1d2a-4f8a-8aa8-86f24e2b92fd' User entered '07 Dec 2020 17:06:33'	System	07 Dec 2020 22:06:36
	System	07 Dec 2020 22:06:36

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-12T23:30:50', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd6f28522-c43a-4c79-9433-17bb6ad6eaf2'	System	13 Dec 2020 04:31:00
User entered 'No (N)'	System	13 Dec 2020 04:31:00

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-12T23:30:54', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd6f28522-c43a-4c79-9433-17bb6ad6eaf2'	System	13 Dec 2020 04:31:00
User entered 'No (N)'	System	13 Dec 2020 04:31:00

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-12T23:30:57', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'd6f28522-c43a-4c79-9433-17bb6ad6eaf2' User entered '12 Dec 2020 23:30:57'	System	13 Dec 2020 04:31:00
	System	13 Dec 2020 04:31:00

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-19T12:17:35', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1b2c6503-38a7-44d4-ba5e-58a1980c4ea5'	System	20 Dec 2020 05:49:40
User entered 'No (N)'	System	20 Dec 2020 05:49:40

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-19T12:17:39', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1b2c6503-38a7-44d4-ba5e-58a1980c4ea5'	System	20 Dec 2020 05:49:40
User entered 'No (N)'	System	20 Dec 2020 05:49:40

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-19T12:17:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '1b2c6503-38a7-44d4-ba5e-58a1980c4ea5' User entered '19 Dec 2020 12:17:42'	System	20 Dec 2020 05:49:40
	System	20 Dec 2020 05:49:40

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-26T18:16:08', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'eb11abd2-93de-446b-80fe-81de6c381e9b' User entered 'No (N)'	System	26 Dec 2020 23:16:21
	System	26 Dec 2020 23:16:21

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-26T18:16:15', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'eb11abd2-93de-446b-80fe-81de6c381e9b'	System	26 Dec 2020 23:16:21
User entered 'No (N)'	System	26 Dec 2020 23:16:21

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2020-12-26T18:16:20', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'eb11abd2-93de-446b-80fe-81de6c381e9b' User entered '26 Dec 2020 18:16:20'	System	26 Dec 2020 23:16:21
	System	26 Dec 2020 23:16:21

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-02T14:03:13', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'c9a0899d-7f9d-48d4-b96d-d205129b4677'	System	02 Jan 2021 19:03:23
User entered 'No (N)'	System	02 Jan 2021 19:03:23

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-02T14:03:16', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'c9a0899d-7f9d-48d4-b96d-d205129b4677'	System	02 Jan 2021 19:03:23
User entered 'No (N)'	System	02 Jan 2021 19:03:23

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-02T14:03:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'c9a0899d-7f9d-48d4-b96d-d205129b4677' User entered '02 Jan 2021 14:03:21'	System	02 Jan 2021 19:03:23
	System	02 Jan 2021 19:03:23

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-09T08:29:42', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'da1790cc-4689-4eb2-aeab-ab76dd0c7ffc'	System	09 Jan 2021 13:29:57
User entered 'No (N)'	System	09 Jan 2021 13:29:57

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-09T08:29:48', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'da1790cc-4689-4eb2-aeab-ab76dd0c7ffc'	System	09 Jan 2021 13:29:57
User entered 'No (N)'	System	09 Jan 2021 13:29:57

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-09T08:29:55', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'da1790cc-4689-4eb2-aeab-ab76dd0c7ffc' User entered '09 Jan 2021 08:29:55'	System	09 Jan 2021 13:29:57
	System	09 Jan 2021 13:29:57

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-16T08:46:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '702f2d62-ce10-4484-a5a7-24d5780229fe' User entered 'No (N)'	System	16 Jan 2021 13:46:12
	System	16 Jan 2021 13:46:12

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-16T08:46:05', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '702f2d62-ce10-4484-a5a7-24d5780229fe' User entered 'No (N)'	System	16 Jan 2021 13:46:12
	System	16 Jan 2021 13:46:12

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-16T08:46:09', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '702f2d62-ce10-4484-a5a7-24d5780229fe' User entered '16 Jan 2021 08:46:09'	System	16 Jan 2021 13:46:12
	System	16 Jan 2021 13:46:12

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-23T14:06:21', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4afd2f6a-f3e7-4ee3-8b96-307589a00652'	System	23 Jan 2021 19:06:38
User entered 'No (N)'	System	23 Jan 2021 19:06:38

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-23T14:06:24', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4afd2f6a-f3e7-4ee3-8b96-307589a00652'	System	23 Jan 2021 19:06:38
User entered 'No (N)'	System	23 Jan 2021 19:06:38

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-23T14:06:34', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4afd2f6a-f3e7-4ee3-8b96-307589a00652'	System	23 Jan 2021 19:06:38
User entered '23 Jan 2021 14:06:34'	System	23 Jan 2021 19:06:38

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-30T07:06:47', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4a2ed5e3-a69a-4732-a875-7820d4b573eb' User entered 'No (N)'	System	30 Jan 2021 12:07:02
	System	30 Jan 2021 12:07:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-30T07:06:53', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4a2ed5e3-a69a-4732-a875-7820d4b573eb' User entered 'No (N)'	System	30 Jan 2021 12:07:02
	System	30 Jan 2021 12:07:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-01-30T07:07:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '4a2ed5e3-a69a-4732-a875-7820d4b573eb' User entered '30 Jan 2021 07:07:00'	System	30 Jan 2021 12:07:02
	System	30 Jan 2021 12:07:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-06T10:49:20', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '878f9d8f-c803-4530-bc99-9c134a431acf'	System	06 Feb 2021 15:49:39
User entered 'No (N)'	System	06 Feb 2021 15:49:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-06T10:49:31', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '878f9d8f-c803-4530-bc99-9c134a431acf'	System	06 Feb 2021 15:49:39
User entered 'No (N)'	System	06 Feb 2021 15:49:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-06T10:49:36', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '878f9d8f-c803-4530-bc99-9c134a431acf'	System	06 Feb 2021 15:49:39
User entered '06 Feb 2021 10:49:36'	System	06 Feb 2021 15:49:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-13T09:38:51', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '18009706-5bb9-4f43-af6d-47bbb092d2b6'	System	13 Feb 2021 14:39:09
User entered 'No (N)'	System	13 Feb 2021 14:39:09

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-13T09:39:03', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '18009706-5bb9-4f43-af6d-47bbb092d2b6'	System	13 Feb 2021 14:39:09
User entered 'No (N)'	System	13 Feb 2021 14:39:09

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-13T09:39:07', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '18009706-5bb9-4f43-af6d-47bbb092d2b6'	System	13 Feb 2021 14:39:09
User entered '13 Feb 2021 09:39:07'	System	13 Feb 2021 14:39:09

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-20T19:04:38', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '759e9746-4cdd-4cb7-8290-f5004d839359'	System	21 Feb 2021 00:09:02
User entered 'No (N)'	System	21 Feb 2021 00:09:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-20T19:04:52', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '759e9746-4cdd-4cb7-8290-f5004d839359'	System	21 Feb 2021 00:09:02
User entered 'No (N)'	System	21 Feb 2021 00:09:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-20T19:04:58', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '759e9746-4cdd-4cb7-8290-f5004d839359'	System	21 Feb 2021 00:09:02
User entered '20 Feb 2021 19:04:58'	System	21 Feb 2021 00:09:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-28T19:53:19-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '41a6abe7-e665-4297-aac3-f424334df9ca'	System	01 Mar 2021 00:53:39
User entered 'No (N)'	System	01 Mar 2021 00:53:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-28T19:53:28-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '41a6abe7-e665-4297-aac3-f424334df9ca'	System	01 Mar 2021 00:53:39
User entered 'No (N)'	System	01 Mar 2021 00:53:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-28T19:53:34-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '41a6abe7-e665-4297-aac3-f424334df9ca'	System	01 Mar 2021 00:53:39
User entered '28 Feb 2021 19:53:34'	System	01 Mar 2021 00:53:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-06T09:30:27-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3d4f644e-c973-4046-b672-aebe5076d73b'	System	08 Mar 2021 05:49:49
User entered 'Yes (Y)'	System	08 Mar 2021 05:49:49

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-06T09:30:20-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3d4f644e-c973-4046-b672-aebe5076d73b'	System	08 Mar 2021 05:49:49
User entered 'No (N)'	System	08 Mar 2021 05:49:49

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Have you experienced any new COVID-19 disease symptoms 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-06T09:30:18-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3d4f644e-c973-4046-b672-aebe5076d73b'	System	08 Mar 2021 05:49:49
User entered 'No (N)'	System	08 Mar 2021 05:49:49

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you had to contact a healthcare provider 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-06T09:30:37-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3d4f644e-c973-4046-b672-aebe5076d73b'	System	08 Mar 2021 05:49:49
User entered 'Yes (Y)'	System	08 Mar 2021 05:49:49

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-06T09:30:45-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3d4f644e-c973-4046-b672-aebe5076d73b'	System	08 Mar 2021 05:49:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Mar 2021 05:49:49

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-06T09:30:54-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '3d4f644e-c973-4046-b672-aebe5076d73b' User entered '06 Mar 2021 09:30:54'	System	08 Mar 2021 05:49:49

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-13T10:02:08-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a0bddaab-ffb2-4a6d-9d99-3ef7144fc2aa'	System	13 Mar 2021 15:02:19
User entered 'No (N)'	System	13 Mar 2021 15:02:19

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-13T10:02:13-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a0bddaab-ffb2-4a6d-9d99-3ef7144fc2aa'	System	13 Mar 2021 15:02:19
User entered 'No (N)'	System	13 Mar 2021 15:02:19

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-13T10:02:16-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'a0bddaab-ffb2-4a6d-9d99-3ef7144fc2aa'	System	13 Mar 2021 15:02:19
User entered '13 Mar 2021 10:02:16'	System	13 Mar 2021 15:02:19

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-20T10:59:21-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f5a81a46-3d2d-435d-b38f-da6930485f37'	System	20 Mar 2021 14:59:32
User entered 'No (N)'	System	20 Mar 2021 14:59:32

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-20T10:59:24-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f5a81a46-3d2d-435d-b38f-da6930485f37'	System	20 Mar 2021 14:59:32
User entered 'No (N)'	System	20 Mar 2021 14:59:32

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-20T10:59:27-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'f5a81a46-3d2d-435d-b38f-da6930485f37'	System	20 Mar 2021 14:59:32
User entered '20 Mar 2021 10:59:27'	System	20 Mar 2021 14:59:32

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-27T14:41:18-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'cfd0eac1-3a92-4496-888b-d62965a50f2f'	System	27 Mar 2021 18:41:29
User entered 'No (N)'	System	27 Mar 2021 18:41:29

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-27T14:41:21-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'cfd0eac1-3a92-4496-888b-d62965a50f2f'	System	27 Mar 2021 18:41:29
User entered 'No (N)'	System	27 Mar 2021 18:41:29

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-03-27T14:41:24-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'cfd0eac1-3a92-4496-888b-d62965a50f2f' User entered '27 Mar 2021 14:41:24'	System	27 Mar 2021 18:41:29
	System	27 Mar 2021 18:41:29

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-04T00:18:11-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '09074256-6da8-4c3f-beb8-6c3aedfb1c4e'	System	04 Apr 2021 04:18:19
User entered 'No (N)'	System	04 Apr 2021 04:18:19

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-04T00:18:14-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '09074256-6da8-4c3f-beb8-6c3aedfb1c4e'	System	04 Apr 2021 04:18:19
User entered 'No (N)'	System	04 Apr 2021 04:18:19

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-04T00:18:17-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '09074256-6da8-4c3f-beb8-6c3aedfb1c4e'	System	04 Apr 2021 04:18:19
User entered '04 Apr 2021 00:18:17'	System	04 Apr 2021 04:18:19

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-11T09:28:52-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '802863d2-4078-4a35-84db-7e73bec6482c'	System	11 Apr 2021 13:29:02
User entered 'No (N)'	System	11 Apr 2021 13:29:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-11T09:28:56-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '802863d2-4078-4a35-84db-7e73bec6482c'	System	11 Apr 2021 13:29:02
User entered 'No (N)'	System	11 Apr 2021 13:29:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-11T09:28:59-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '802863d2-4078-4a35-84db-7e73bec6482c' User entered '11 Apr 2021 09:28:59'	System	11 Apr 2021 13:29:02
	System	11 Apr 2021 13:29:02

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-18T16:42:20-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e1b203ea-b56b-44f2-8782-48da91c8b1d7'	System	18 Apr 2021 20:42:34
User entered 'No (N)'	System	18 Apr 2021 20:42:34

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-18T16:42:24-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e1b203ea-b56b-44f2-8782-48da91c8b1d7'	System	18 Apr 2021 20:42:34
User entered 'No (N)'	System	18 Apr 2021 20:42:34

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-18T16:42:27-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: 'e1b203ea-b56b-44f2-8782-48da91c8b1d7'	System	18 Apr 2021 20:42:34
User entered '18 Apr 2021 16:42:27'	System	18 Apr 2021 20:42:34

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-24T11:37:56-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0e40401f-306f-4f5d-b2a1-0566515e720f'	System	25 Apr 2021 17:58:39
User entered 'No (N)'	System	25 Apr 2021 17:58:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

Have you been exposed to someone with 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 (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-24T11:37:59-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0e40401f-306f-4f5d-b2a1-0566515e720f'	System	25 Apr 2021 17:58:39
User entered 'No (N)'	System	25 Apr 2021 17:58:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-04-24T11:38:01-04:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '0e40401f-306f-4f5d-b2a1-0566515e720f' User entered '24 Apr 2021 11:38:01'	System	25 Apr 2021 17:58:39
	System	25 Apr 2021 17:58:39

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:45:26

US3152175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:45:26
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:45:26

US3152175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:53

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 15:37:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-28T19:53:44-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '91a7dfee-3b58-49ac-bd5f-dcc1b51439ef'	System	01 Mar 2021 00:53:50
User entered 'No (N)'	System	01 Mar 2021 00:53:50

US3152175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:37:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BF16CD41-C1C4-495D-B3C7-08BB23BBE25F)', Time: '2021-02-28T19:53:48-05:00', User OID: 'PatientReportedOutcome (US3152175)', ODM File OID: '91a7dfee-3b58-49ac-bd5f-dcc1b51439ef' User entered '28 Feb 2021 19:53:48'	System	01 Mar 2021 00:53:50
	System	01 Mar 2021 00:53:50

US3152175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:50
User entered 'Yes (Y)'	Jemario Blackwell (b) (4) (b) (4)	11 Dec 2020 20:39:01

US3152175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:50
User entered '03 Nov 2020'	Jemario Blackwell (b) (4) (b) (4)	11 Dec 2020 20:39:01

US3152175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:50
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:39:01

US3152175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:50
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	11 Dec 2020 20:39:01

US3152175

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:50
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:39:05

US3152175

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:59:05
User entered '1'	System	11 Dec 2020 20:39:05

US3152175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Jemario Blackwell (b) (4) (b) (4)	11 Dec 2020 20:42:09

US3152175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '11 Dec 2020'	Jemario Blackwell (b) (4) (b) (4)	11 Dec 2020 20:42:09

US3152175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:42:09

US3152175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	11 Dec 2020 20:42:09

US3152175

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:42:14

US3152175

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User entered 'I'	System	11 Dec 2020 20:42:14

US3152175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	06 Jan 2021 21:53:53

US3152175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '6 Jan 2021'	Devan Myers (b) (4) (b) (4)	06 Jan 2021 21:53:53

US3152175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	06 Jan 2021 21:53:53

US3152175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Devan Myers (b) (4)	06 Jan 2021 21:53:53

US3152175

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	06 Jan 2021 21:53:43

US3152175

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User entered '1'	System	06 Jan 2021 21:53:43

US3152175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	05 Feb 2021 19:18:04

US3152175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '5 Feb 2021'	Devan Myers (b) (4)	05 Feb 2021 19:18:04

US3152175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	05 Feb 2021 19:18:04

US3152175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Devan Myers (b) (4)	05 Feb 2021 19:18:04

US3152175

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	05 Feb 2021 19:18:08

US3152175

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:25
User entered '1'	System	05 Feb 2021 19:18:08

US3152175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:34:32

US3152175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:34:32

US3152175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Mar 2021 16:34:32

US3152175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered 'VISIT4'	System	22 Mar 2021 16:34:32

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'No (N)'	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered empty.	System	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered empty.	System	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered empty.	System	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered empty.	System	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Priscilla Buahin (b) (4) (b) (4)	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered empty.	System	31 Mar 2021 20:20:09

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24

US3152175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24

US3152175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:36:49

US3152175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:36:49

US3152175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:37:11

US3152175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:37:11

US3152175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '09:31'	(b) (4), (b) (6)	22 Mar 2021 16:37:11

US3152175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered '22 Mar 2021 09:31'	System	22 Mar 2021 16:37:11

US3152175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:37:20

US3152175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:12:24
User entered '1'	System	22 Mar 2021 16:37:20

US3152175

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 17:11:07

US3152175

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '6 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 17:11:07

US3152175

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Apr 2021 17:11:07

US3152175

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:11:07

US3152175

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 17:11:12

US3152175

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:11:12

US3152175

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Query 'Visit date inconsistent with pharmacy source and IRT. Please review and update ' canceled (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 15:32:16
User opened query 'Visit date inconsistent with pharmacy source and IRT. Please review and update ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:08:23
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:03

US3152175

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:03

US3152175

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[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 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Clinic (Clinic)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:03

US3152175

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'UNBLND_DECIDE'	System	31 Dec 2020 14:57:03

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:20

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[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 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '0'	Priscilla Buahin (b) (4)	09 Mar 2021 22:24:24
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:33:47

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	31 Dec 2020 14:57:20

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	Priscilla Buahin (b) (4)	09 Mar 2021 22:24:24
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 12:33:47

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:20

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Placebo (Placebo)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:20

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:15:45
User entered 'Placebo (Placebo)'	Devan Myers (b) (4)	31 Dec 2020 14:57:20
	(b) (4)	

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:15:45
User entered 'Placebo (Placebo)'	Devan Myers (b) (4)	31 Dec 2020 14:57:20
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:57:20

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '1'	System	31 Dec 2020 14:57:20

US3152175

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '1'	System	31 Dec 2020 14:57:20

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '147.5' cm	Devan Myers (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '63.5' kg	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '29.18702'	System	31 Dec 2020 14:58:33
DataPoint set to visible.	System	31 Dec 2020 14:57:20

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '147.5' cm	Devan Myers (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '63.5' kg	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '29.18702'	System	31 Dec 2020 14:58:33
DataPoint set to visible.	System	31 Dec 2020 14:57:20

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User accepted default value 'Pre-Dose (PREDOSE)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '15:40'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '30 Dec 2020 15:40'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '37.0' C	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Oral (Oral)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '63'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'bpm'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '14'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'breaths/min'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '120'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'mmHg'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '81'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'mmHg'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '147.5' cm	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '63.5' kg	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '29.18702'	System	31 Dec 2020 14:58:33
DataPoint set to visible.	System	31 Dec 2020 14:57:20

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User accepted default value 'Post-Dose (POSTDOSE)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '16:40'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '30 Dec 2020 16:40'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '36.8' C	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Oral (Oral)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '61'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'bpm'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '16'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'breaths/min'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '126'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'mmHg'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '82'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:33

US3152175

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'mmHg'	System	31 Dec 2020 14:58:33

US3152175

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Jan 2021 22:14:09
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:42

US3152175

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty; reason for change New Information	(b) (4), (b) (6)	26 Jan 2021 22:14:09
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:58:42

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	Devan Myers (b) (4)	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'mRNA-1273'	System	31 Dec 2020 14:59:00
DataPoint set to visible.	System	31 Dec 2020 14:57:20

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 13JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:17:24
Query 'Per IRT, Subject had Open Label Day1 Treatment on 13JAN2021. Please review and reconcile.' answered with 'Treatment was assigned to subject on 29DEC2021. Unblinded team has submitted a DCF with correct date.' (Site from DM).	Priscilla Buahin (b) (4)	09 Apr 2021 19:37:21
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 13JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:01:57
Query 'subject dosed 26Jan2021 per source' canceled (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:41:38
User opened query 'subject dosed 26Jan2021 per source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:09:38
User entered '30 Dec 2020'	Devan Myers (b) (4)	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the treatment time? (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
Query 'time inconsistent with pharmacy source for IP prep and administration . Please review and reconcile ' canceled (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:41:39
User opened query 'time inconsistent with pharmacy source for IP prep and administration . Please review and reconcile ' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:10:29
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 18:09:43
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:09:40
User entered '16:10'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '30 Dec 2020 16:10'	System	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'ONCE'	System	31 Dec 2020 14:59:00

US3152175

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

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered 'INTRAMUSCULAR'	System	31 Dec 2020 14:59:00

US3152175

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	Devan Myers (b) (4)	31 Dec 2020 14:59:14

US3152175

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:14

US3152175

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '15:46'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:14

US3152175

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '30 Dec 2020 15:46'	System	31 Dec 2020 14:59:14

US3152175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:27

US3152175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '30 Dec 2020'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:27

US3152175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '16:04'	Devan Myers (b) (4) (b) (4)	31 Dec 2020 14:59:27

US3152175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '30 Dec 2020 16:04'	System	31 Dec 2020 14:59:27

US3152175

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

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	Devan Myers (b) (4)	31 Dec 2020 14:59:33

US3152175

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

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:04:47
User entered '1'	System	31 Dec 2020 14:59:33

US3152175

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:53:34

US3152175

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
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).	System	16 Mar 2021 14:38:12
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 by data change (Site from System).	System	16 Mar 2021 14:38:12
User entered '06 Jan 2021' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	16 Mar 2021 14:38:12
Amendment Manager: User opened 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).	System	17 Feb 2021 00:51:55
User entered '30 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 21:53:34

US3152175

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Jan 2021 21:53:34

US3152175

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:53:34

US3152175

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:53:41

US3152175

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User entered '1'	System	26 Jan 2021 21:53:41

US3152175

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:48:19
User entered '1'	System	26 Jan 2021 21:53:41
DataPoint set to visible.	System	26 Jan 2021 21:53:41

US3152175

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:53:57

US3152175

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 21:53:57

US3152175

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[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 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Jan 2021 21:53:57

US3152175

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'OLD29'	System	26 Jan 2021 21:53:57

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User accepted default value 'Pre-Dose (PREDOSE)'		26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '14:13'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered '26 Jan 2021 14:13'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '36.4' C	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '73'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'bpm'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '14'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'breaths/min'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '135'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'mmHg'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '83'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'mmHg'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User accepted default value 'Post-Dose (POSTDOSE)'		26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '15:15'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered '26 Jan 2021 15:15'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '36.6' C	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '61'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'bpm'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '15'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'breaths/min'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '124'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'mmHg'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '76'	(b) (4), (b) (6)	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'mmHg'	System	26 Jan 2021 21:55:19

US3152175

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:55:27

US3152175

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 21:55:27

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'mRNA-1273'	System	26 Jan 2021 21:56:06
DataPoint set to visible.	System	26 Jan 2021 21:53:41

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '14:45'	(b) (4), (b) (6)	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered '26 Jan 2021 14:45'	System	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'ONCE'	System	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 21:56:06

US3152175

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:56:13

US3152175

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:09:24
User entered '1'	System	26 Jan 2021 21:56:13

US3152175

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:34
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Feb 2021 20:26:36

US3152175

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:34
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '2 Feb 2021'	Devan Myers (b) (4) (b) (4)	02 Feb 2021 20:26:36

US3152175

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:34
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	02 Feb 2021 20:26:36

US3152175

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:34
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered empty.	Devan Myers (b) (4) (b) (4)	02 Feb 2021 20:26:36

US3152175

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:34
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'Yes (Y)'	Devan Myers (b) (4)	02 Feb 2021 20:26:40

US3152175

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:34
User entered '1'	System	02 Feb 2021 20:26:40

US3152175

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 16:41:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 16:41:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	06 Apr 2021 16:41:33
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 13:54:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:54:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 13:51:10

US3152175

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '22 Mar 2021' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	06 Apr 2021 16:41:33
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)	30 Mar 2021 07:55:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:54:52
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Date is correct' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:51:31
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	22 Mar 2021 13:51:10
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 13:51:10

US3152175

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[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 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	06 Apr 2021 16:41:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:54:52
User entered 'Clinic (Clinic)'		22 Mar 2021 13:51:10

US3152175

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered 'OLD57'	System	06 Apr 2021 16:41:33
User entered empty.	System	22 Mar 2021 13:54:52
User entered 'OLD57'	System	22 Mar 2021 13:51:10

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '09:24'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered '22 Mar 2021 09:24'	System	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '36.4' C	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '63'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered 'bpm'	System	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '14'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered 'breaths/min'	System	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '114'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered 'mmHg'	System	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '76'	(b) (4), (b) (6)	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered 'mmHg'	System	22 Mar 2021 16:32:07

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42

US3152175

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42

US3152175

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:32:11

US3152175

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 16:32:11

US3152175

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:33:40

US3152175

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 16:33:40

US3152175

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:15
User entered '09:31'	(b) (4), (b) (6)	22 Mar 2021 16:33:40

US3152175

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:35:42
User entered '22 Mar 2021 09:31'	System	22 Mar 2021 16:33:40

US3152175

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:28:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:55:02
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Yes (Y)' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:05:46
User entered 'No (N)'	(b) (4), (b) (6)	27 Feb 2021 18:06:08

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:28
User entered 'USA-US073-2021-mRNA-1273-P301000009'	System	08 Mar 2021 15:29:32
User entered 'New'	(b) (4), (b) (6)	08 Mar 2021 15:29:32

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 20:12:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 20:12:11
Data point term sent to Coder	System	05 Mar 2021 20:10:50
User entered 'cholecystitis'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Signature has been broken.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:41
User entered '02 Mar 2021' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:41
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Grade 4 (Grade 4)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '1'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '04 Mar 2021'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Not Applicable (NOT APPLICABLE)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

None

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #9 and 10 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 22:29:23
Query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #9 and 10 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'updated.' (Site from DM). Signature has been broken.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '1' reason for change: Per Query Resolution User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #9 and 10 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 17:13:37
User entered '0'	(b) (4)	06 Apr 2021 17:13:21
	(b) (4)	06 Apr 2021 17:13:21
	(b) (4)	03 Apr 2021 04:36:15
	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '1'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

US3152175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User closed query 'Please review date entered 030Mar2021.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 01:52:14
Query 'Please review date entered 030Mar2021.' answered with 'PER MEDICAL RECORDS ABDOMINAL PAIN ONSET 02 MAR 2021 MEDICAL EVALUATION 03 MAR 2021' (Site from CRA).	Oyebisi Olanrewaju (b) (4)	25 Mar 2021 18:21:34
User entered 'SITE NOTIFIED OF EMERGENT CHOLECYSTECTOMY PERFORMED 03 MAR 2021 EVENT REPORTED TO SITE ON 05 MAR 2021. REPORTS SUDDEN ONSET ABDOMINAL PAIN 02 MAR 2021. PRESENTED TO ER FOR EVALUATION 03 MAR 2021. RELEVANT LABS INCLUDE AST 1002 U/L AND ALT 623 U/L ON 03 MAR 2021 AT 0708 AND RELEVANT DIAGNOSTIC STUDY INCLUDES ULTRASOUND RIGHT ABDOMINAL QUADRANT IMPRESSION READS AS FOLLOWS CHOLELITHIASIS ASSOCIATED MILD GALLBLADDER WALL THICKENING COULD BE DUE TO MILD ACUTE CHOLECYSTITIS WITH MURPHY'S SIGN DIFFICULT TO ASSESS BECAUSE PATIENT WAS MEDICATED. CLINICAL CORRELATION SUGGESTED. ADMITTING DIAGNOSIS CHOLECYSTITIS. CHOLECYSTECTOMY 03 MAR 2021. 23 HOUR HOSPITAL STAY. ALT 850 AST 399 04 MAR 2021 AT 0444. MEDICAL RECORDS RECEIVED AND REVIEWED 23 MAR 2021.' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	25 Mar 2021 18:14:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE NOTIFIED OF EMERGENT CHOLECYSTECTOMY PERFORMED 030MAR 2021 EVENT REPORTED TO SITE ON 05 MAR 2021. REPORTS SUDDEN ONSET ABDOMINAL PAIN 02 MAR 2021. PRESENTED TO ER FOR EVALUATION 03 MAR 2021. RELEVANT LABS INCLUDE AST 1002 U/L AND ALT 623 U/L ON 03 MAR 2021 AT 0708 AND RELEVANT DIAGNOSTIC STUDY INCLUDES ULTRASOUND RIGHT ABDOMINAL QUADRANT IMPRESSION READS AS FOLLOWS CHOLELITHIASIS ASSOCIATED MILD GALLBLADDER WALL THICKENING COULD BE DUE TO MILD ACUTE CHOLECYSTITIS WITH MURPHY'S SIGN DIFFICULT TO ASSESS BECAUSE PATIENT WAS MEDICATED. CLINICAL CORRELATION SUGGESTED. ADMITTING DIAGNOSIS CHOLECYSTITIS. CHOLECYSTECTOMY 03 MAR 2021. 23 HOUR HOSPITAL STAY. ALT 850 AST 399 04 MAR 2021 AT 0444. MEDICAL RECORDS RECEIVED AND REVIEWED 23 MAR 2021.' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	25 Mar 2021 18:13:25
User opened query 'Please review date entered 030Mar2021.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 17:52:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 12:44:54
User closed query 'Per DM CLR: Narrative = CHOLECYSTECTOMY 03 MAR 2020. Please review and correct YEAR as appropriate ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:34:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' answered with 'updated after review of medical records ' (Site from Safety).	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:19:18
User entered 'SITE notified OF EMERGENT CHOLECYSTECTOMY PERFORMED 030MAR 2021 ON 05 MAR 2021. REPORTS SUDDEN ONSET ABDOMINAL PAIN 02 mar 2021. presented to ER for EVALUATION 03 mar 2021. Relevant labs include AST 1002 U/L and ALT 623 U/L on 03 mar 2021 at 0708 and relevant diagnostic study includes ultrasound right abdominal quadrant impression reads as follows cholelithiasis associated mild gallbladder wall thickening could be due to mild acute cholecystitis with murphy's sign difficult to assess because patient was medicated. clinical correlation suggested. Admitting diagnosis CHOLECYSTITIS. CHOLECYSTECTOMY 03 MAR 2021. 23 HOUR HOSPITAL STAY. ALT 850 AST 399 04 mar 2021 at 0444. MEDICAL RECORDS received and reviewed 23 mar 2021.'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:18:56
reason for change: Per Query Resolution Query 'Per DM CLR: Narrative = CHOLECYSTECTOMY 03 MAR 2020. Please review and correct YEAR as appropriate ' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	22 Mar 2021 13:42:54
		22 Mar 2021 13:42:50
User entered 'SITE OF EMERGENT CHOLECYSTECTOMY PERFORMED 030MAR 2021 ON 05 MAR 2021. REPORTS SUDDEN ONSET ABDOMINAL PAIN, EVALUATION REVEALED CHOLECYSTITIS. CHOLECYSTECTOMY 03 MAR 2021. 23 HOUR HOSPITAL STAY. MEDICAL RECORDS PENDING.' reason for change: Data Entry Error		22 Mar 2021 13:42:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = CHOLECYSTECTOMY 03 MAR 2020. Please review and correct YEAR as appropriate ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 06:04:46
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:07:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 20:07:45
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'No results available yet. Medical records pending' (Site from Safety).	Priscilla Buahin (b) (4) (b) (4)	16 Mar 2021 14:34:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 14:28:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Site of emergent cholecystectomy performed 030mar 2021 on 05 mar 2021. Reports sudden onset abdominal pain, evaluation revealed cholecystitis. Cholecystectomy 03 mar 2020. 23 hour hospital stay. Medical records pending.'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:10:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 20:10:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 20:10:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 20:10:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:26:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:26:48
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Data point term sent to Coder	System	07 Apr 2021 15:31:47
Coding entries removed.	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:31:09
User entered 'POST PROCEDURE PAIN (CHOLECYSTECTOMY)' reason for change: Per Query Resolution	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:31:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:51:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:51:39
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of POST PROCEDURE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. '(Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:34:31
Data point term sent to Coder	System	24 Mar 2021 13:25:04
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of POST PROCEDURE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'reviewed and updated ' (Site from DM).	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:24:12
Coding entries removed.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:24:03
Signature has been broken.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:24:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'POST PROCEDURE (cholecystectomy) PAIN' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:24:03
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of POST PROCEDURE PAIN. Please reconcile with the ConMed eCRF so there is an appropriate match. '(Site from DM).	(b) (4), (b) (6)	21 Mar 2021 06:04:55
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 20:14:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 20:14:57
Data point term sent to Coder	System	05 Mar 2021 20:13:54
User entered 'post procedure pain'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	05 Mar 2021 20:13:16
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	05 Mar 2021 20:13:16
User entered '03 Mar 2021' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:13:16
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	05 Mar 2021 20:12:57
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	05 Mar 2021 20:12:57
User entered '03 Mar 2020'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User entered empty.	System	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 17:12:37
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 17:12:37
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 17:12:37
User entered '9 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 17:12:37
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User entered empty.	System	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Not Applicable (NOT APPLICABLE)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '1'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 17:12:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 17:12:37
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

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 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:03:13
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User entered '0'	System	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34
User entered '1'	System	05 Mar 2021 20:12:57

US3152175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:28:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:15:34

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:28:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:55:02
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:14:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:16:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:16:31
Data point term sent to Coder	System	14 Aug 2020 17:16:04
User entered 'ATENOLOL'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'HYPERTENSION'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '25'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mg (mg)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once daily (QD)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 10:04:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Brandon Essink (b) (4)	14 Aug 2020 17:15:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:15:35
User entered '01 Jul 2020'	Brandon Essink (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:15:35

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:59:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:59:21
Data point term sent to Coder	System	14 Aug 2020 17:17:06
User entered 'DIVALPROEX'	Brandon Essink (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'ANXIETY'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '750'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mg (mg)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once daily (QD)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 10:04:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Brandon Essink (b) (4)	14 Aug 2020 17:17:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:16:54
User entered 'UN UNK 2019'	Brandon Essink (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:16:54

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
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)	20 Aug 2020 21:24:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 21:24:25
Data point term sent to Coder Coding entries removed.	System Juliana DeVito (b) (4)	20 Aug 2020 21:23:30 20 Aug 2020 21:23:29
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)	14 Aug 2020 17:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:18:18
Data point term sent to Coder User entered 'MULTIVITAMIN'	System Brandon Essink (b) (4)	14 Aug 2020 17:18:08 14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'nutritional supplement' reason for change: Data Entry Error	Juliana DeVito (b) (4)	20 Aug 2020 21:23:29
User entered 'GENERAL HEALTH'	Brandon Essink (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '1'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'tablet (TABLET)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once daily (QD)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 10:04:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Brandon Essink (b) (4)	14 Aug 2020 17:18:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:17:46
User entered 'UN Mar 2020'	Brandon Essink (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 17:17:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:21:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:21:18
Data point term sent to Coder	System	14 Aug 2020 17:20:13
User entered 'TUMS'	Brandon Essink (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Brandon Essink (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '2'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'tablet (TABLET)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'as needed (PRN)' reason for change: Data Entry Error	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:40
User entered 'once daily (QD)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 10:04:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Brandon Essink (b) (4)	14 Aug 2020 17:20:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:20:26
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 17:20:26
User entered 'UN UNK 2010' reason for change: Data Entry Error	Brandon Essink (b) (4)	14 Aug 2020 17:20:26
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 17:20:12
User entered empty.	Brandon Essink (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:21:40
User entered '1'	System	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:21:40
User entered '1'	System	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:21:40
User entered '804 (804)'	System	14 Aug 2020 17:20:12

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
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: LANSOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:23:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 17:23:27
Data point term sent to Coder	System	14 Aug 2020 17:22:17
User entered 'LANSOPRAZOLE'	Brandon Essink (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Brandon Essink (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '30'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mg (mg)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'as needed (PRN)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 10:04:58
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Brandon Essink (b) (4)	14 Aug 2020 17:21:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 17:21:21
User entered 'UN UNK 2010'	Brandon Essink (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Brandon Essink (b) (4) (b) (4)	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 17:21:21

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 21:23:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 21:23:27
Data point term sent to Coder	System	20 Aug 2020 21:22:29
User entered 'vitamin d3'	Juliana DeVito (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'nutritional supplement'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '25'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'ug (ug)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once daily (QD)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:21:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Juliana DeVito (b) (4)	20 Aug 2020 21:23:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:22:06
User entered 'UN UNK 2019'	Juliana DeVito (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:22:06

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
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)	20 Aug 2020 21:24:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Aug 2020 21:24:25
Data point term sent to Coder	System	20 Aug 2020 21:23:30
User entered 'vitamin C'	Juliana DeVito (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'nutritional supplement'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '500'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mg (mg)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once daily (QD)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:21:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Juliana DeVito (b) (4)	20 Aug 2020 21:22:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:22:46
User entered 'un UNK 2019'	Juliana DeVito (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:22:46

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 20:15:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 20:15:57
Data point term sent to Coder	System	05 Mar 2021 20:14:56
User entered 'tylenol'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'post procedure pain (cholecystectomy)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '1000'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mg (mg)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'as needed (PRN)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Oral (ORAL)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '04 Mar 2021'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 20:14:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:48:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:48:35
Data point term sent to Coder	System	24 Mar 2021 13:21:02
User entered 'Toradol'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'cholecystitis'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '15'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mg (mg)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once (ONCE)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Intravenous (INTRAVENOUS)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User entered empty.	System	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User entered empty.	System	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:06
User entered empty.	System	24 Mar 2021 13:20:37

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 13:24:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 13:24:34
Data point term sent to Coder	System	24 Mar 2021 13:24:03
User entered 'zosyn'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'cholecystitis'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '4.5'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'g (g)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once (ONCE)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Intravenous (INTRAVENOUS)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User entered empty.	System	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User entered empty.	System	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:08
User entered empty.	System	24 Mar 2021 13:23:04

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 15:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Apr 2021 15:33:40
Data point term sent to Coder	System	07 Apr 2021 15:32:48
User entered 'influenza vaccine'	Juliana DeVito (b) (4)	07 Apr 2021 15:32:38
	(b) (4)	

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	07 Apr 2021 15:32:38
	(b) (4)	

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'influenza prophylaxis'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0.5'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'mL (mL)'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'once (ONCE)'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Intramuscular (INTRAMUSCULAR)'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '01 Oct 2020'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '0'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '01 Oct 2020'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User entered empty.	System	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User entered empty.	System	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:21:10
User entered empty.	System	07 Apr 2021 15:32:38

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:28:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:55:02
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Yes (Y)' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:13:33
User entered 'No (N)'	(b) (4), (b) (6)	27 Feb 2021 18:06:00

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered '03 Mar 2021'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:13:54

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'cholecystectomy'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:13:54

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered 'Adverse Event (AE)'	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:13:54

US3152175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:53

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:13:07
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Mar 2021 20:13:54

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:57
User entered 'USA-US073-2021-MRNA-1273-P301000009'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Brandon'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Essink'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '3319 N 107th'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Omaha'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '68134'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'US'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 16:07:47
User entered '4'	System	26 Mar 2021 12:34:31
User entered '3'	System	25 Mar 2021 12:45:47
User entered '2'	System	23 Mar 2021 14:52:35
User entered '1'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:57
User entered 'USA-US073-2021-MRNA-1273-P301000009'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Brandon'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Essink'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '3319 N 107th'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Omaha'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '68134'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'US'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 16:07:47
User entered '4'	System	26 Mar 2021 12:34:31
User entered '3'	System	25 Mar 2021 12:45:47
User entered '2'	System	23 Mar 2021 14:52:35
User entered '1'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '08/Mar/2021 10:35'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered '1'		08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:57
User entered 'USA-US073-2021-MRNA-1273-P301000009'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Brandon'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Essink'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '3319 N 107th'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Omaha'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '68134'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'US'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 16:07:47
User entered '4'	System	26 Mar 2021 12:34:31
User entered '3'	System	25 Mar 2021 12:45:47
User entered '2'	System	23 Mar 2021 14:52:35
User entered '1'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:28:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '23/Mar/2021 10:52'	System	23 Mar 2021 14:52:35

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:28:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'I'		23 Mar 2021 14:52:35

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:57
User entered 'USA-US073-2021-MRNA-1273-P301000009'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Brandon'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Essink'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '3319 N 107th'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Omaha'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '68134'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'US'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 16:07:47
User entered '4'	System	26 Mar 2021 12:34:31
User entered '3'	System	25 Mar 2021 12:45:47
User entered '2'	System	23 Mar 2021 14:52:35
User entered '1'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:28:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '25/Mar/2021 08:45'	System	25 Mar 2021 12:45:47

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:28:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '1'	(b) (4), (b) (6)	25 Mar 2021 12:45:47

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:57
User entered 'USA-US073-2021-MRNA-1273-P301000009'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Brandon'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Essink'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '3319 N 107th'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Omaha'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '68134'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'US'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 16:07:47
User entered '4'	System	26 Mar 2021 12:34:31
User entered '3'	System	25 Mar 2021 12:45:47
User entered '2'	System	23 Mar 2021 14:52:35
User entered '1'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:28:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '26/Mar/2021 08:34'	System	26 Mar 2021 12:34:31

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:28:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 12:34:31

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:34:57
User entered 'USA-US073-2021-MRNA-1273-P301000009'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Yes (Y)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'No (N)'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Brandon'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Essink'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '3319 N 107th'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered 'Omaha'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 15:35:03
User entered '68134'	System	08 Mar 2021 15:29:32

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Mar 2021 14:52:38
User entered 'US'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 16:07:47
User entered '4'	System	26 Mar 2021 12:34:31
User entered '3'	System	25 Mar 2021 12:45:47
User entered '2'	System	23 Mar 2021 14:52:35
User entered '1'	System	08 Mar 2021 15:35:13

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:28:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '07/Apr/2021 12:07'	System	07 Apr 2021 16:07:47

US3152175

Folder: SAE USA-US073-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:28:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:15:48
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 16:07:47