

US3152413 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:20:38

All time stamps listed in this document are displayed in GMT

US3152413

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Participant ID

US3152413

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

US3152413

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3152413

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3152413

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3152413

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Condition	CERVICAL DISC COMPRESSION C5-C6
Start date (dd MMM yyyy)	UN MAY 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Condition	MOTOR VEHICLE ACCIDENT
Start date (dd MMM yyyy)	UN MAY 2019
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 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:08
Height (xxx.x)	165 cm
Weight (xxx.x)	103.7 kg
BMI (xxx.x)	38.08999 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 04:10:32

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Date of assessment (dd MMM yyyy) 29 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	29 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 04:10:33

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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

OFFICE WORK SURROUNDED
BY MULTIPLE EMPLOYEES

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 04:10:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

What was the date of randomization? (dd MMM yyyy) 29 SEP 2020

What was the participant's randomization number? 112768

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 04:10:33

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:08
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

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 (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:48
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3152413

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 29 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 10:18 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 10:18

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

09:47 (24 HR)

Collection date and time (derived)

29 SEP 2020 09:47

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	29 SEP 2020 09:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 10:51

PC Open Date & Time

29 SEP 2020 10:38

PC Close Date & Time

29 SEP 2020 13:08

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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 97.9 °F

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

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

PC Time Stamp	29 SEP 2020 15:36
PC Open Date & Time	29 SEP 2020 14:03
PC Close Date & Time	30 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 13:32

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 14:18

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

02 OCT 2020 12:50

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 13:26

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 17:53

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 10:50

PC Open Date & Time

29 SEP 2020 10:38

PC Close Date & Time

29 SEP 2020 13:08

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

Yes ☐

No ☒

Please record - **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

29 SEP 2020 15:29

PC Open Date & Time

29 SEP 2020 14:03

PC Close Date & Time

30 SEP 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 13:27

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

35

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

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 14:19

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

28

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:47

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 13:23

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 17:50

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:51
PC Open Date & Time	29 SEP 2020 10:38
PC Close Date & Time	29 SEP 2020 13:08

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 15:29
PC Open Date & Time	29 SEP 2020 14:03
PC Close Date & Time	30 SEP 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 13:28
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

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 ☒

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EAB) (1725)

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US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 14:19
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:47
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:23
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:51
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 06 OCT 2020 18:35

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3152413

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 18:35
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3152413

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

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

Visit date (dd MMM yyyy)	27 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

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)	27 OCT 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 13:30
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 15:07
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3152413

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	27 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

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) 27 OCT 2020

What was the treatment time? (00:00-23:59) 14:37 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 14:37

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

US3152413

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

13:34 (24 HR)

Collection date and time (derived)

27 OCT 2020 13:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:33	27 OCT 2020 14:33
Nasopharyngeal Swab 2	No		

US3152413

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 15:10

PC Open Date & Time

27 OCT 2020 14:57

PC Close Date & Time

27 OCT 2020 17:27

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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 97.6 °F

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

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

PC Time Stamp	27 OCT 2020 18:29
PC Open Date & Time	27 OCT 2020 18:22
PC Close Date & Time	28 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 OCT 2020 12:45

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 17:37

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 12:46

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

31 OCT 2020 14:18

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

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.

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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

01 NOV 2020 13:24

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

02 NOV 2020 12:48

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 15:09

PC Open Date & Time

27 OCT 2020 14:57

PC Close Date & Time

27 OCT 2020 17:27

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

27 OCT 2020 18:29

PC Open Date & Time

27 OCT 2020 18:22

PC Close Date & Time

28 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

65

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

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

Yes ☒

No ☐

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

65

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 12:46

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

63

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

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

Yes ☒

No ☐

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 17:37

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

60

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

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

Yes ☒

No ☐

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

60

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 12:46

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 14:20

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

40

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 13:25

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 12:48

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 15:09
PC Open Date & Time	27 OCT 2020 14:57
PC Close Date & Time	27 OCT 2020 17:27

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 18:29
PC Open Date & Time	27 OCT 2020 18:22
PC Close Date & Time	28 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 12:47
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 17:37
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 12:47
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 14:18
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 13:25
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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 ☒

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

25

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

PC Time Stamp

03 NOV 2020 17:23

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

25

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

PC Time Stamp

04 NOV 2020 18:07

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

05 NOV 2020 14:04

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 03 NOV 2020 17:23

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 NOV 2020 17:23
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 NOV 2020 14:04
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3152413

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:32

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 13:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3152413

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

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.

US3152413

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 NOV 2020

Collection time (00:00-23:59)

13:36 (24 HR)

Collection date and time (derived)

24 NOV 2020 13:36

US3152413

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 04:10:33

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 19:58:49
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 18:07:07
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 DEC 2020 21:01:05
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 16:40:13
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 DEC 2020 19:45:29
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 19:13:58
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 19:14:07

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 13:05:56
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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	21 JAN 2021 16:49:11
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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	28 JAN 2021 13:36:15
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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	04 FEB 2021 18:27:01
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 10:12:04

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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	18 FEB 2021 09:19:29
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 23:40:11

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 11:57:25

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 20:34:22
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 20:27:43

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 19:18:15

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 18:10:41

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	08 APR 2021 10:21:29
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 17:53:24

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 03:16:31

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 00:02:33

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	11 AUG 2022 00:01
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Patient Cloud Close Date & Time	15 AUG 2022 23:59
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US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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°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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2022 00:01
Patient Cloud Close Date & Time	05 DEC 2022 23:59

US3152413

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:20:38

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
Yes	Yes	06 MAR 2021 11:57:55

US3152413

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:08:16

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3152413

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152413

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3152413

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

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.

US3152413

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Date of Contact	14 JAN 2021
Time of Contact	13:06
Date and Time of Contact (derived)	14 JAN 2021 13:06
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3152413

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

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

Visit date (dd MMM yyyy)	6 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	UNBLND_DECIDE
------------	---------------

US3152413

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Date of updated informed consent (dd MMM yyyy) 6 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 6 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3152413

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	14:39 (24 HR)
Collection date and time (derived)	6 JAN 2021 14:39

US3152413

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	14:33
Collection Date and Time (derived)	6 JAN 2021 14:33

US3152413

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Mar 2021 02:15:03

Generated On: 09 Jun 2021 15:20:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

AEID

Adverse event

SINUS INFECTION

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)

19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

AEID

Adverse event

INJECTION SITE REDNESS -
NON-URTICARIAL

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)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

AEID	
Adverse event	PANIC ATTACKS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

AEID

Adverse event

YEAST INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

AEID

Adverse event

WORSENING OF CERVICAL
DISC COMPRESSION WITH
RADICULOPATHY

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)

3 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

AEID	USA-US073-2021-MRNA-1273-P30 1000012
Adverse event	CHOLECYSTITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT INFORMED SITE OF ADMISSION POST CHOLECYSTECTOMY. INDICATION FOR CHOLECYSTECTOMY WAS CHOLECYSTITIS. MEDICAL RECORDS PENDING,

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 02:25:17

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Apr 2021 21:12:06

Generated On: 09 Jun 2021 15:20:38

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

Yes ☒

No ☐

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

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY -
MIGRAINES

Dose per administration 10

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 (1)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication BLISOVI

Prophylaxis Yes ☐
No ☒

Indication POLYCYSTIC OVARIAN SYNDROME

Dose per administration 1/.02

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MG/MG

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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EAB) (1725)

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US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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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US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication CLINDAMYCIN 1.0%

Prophylaxis Yes ☐
No ☒

Indication ACNE

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

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 (4)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication TRETINOIN

Prophylaxis Yes ☐
No ☒

Indication ACNE

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication SINUS INFECTION

Dose per administration 100

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 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 400

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 (8)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE REDNESS

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication YEAST INFECTION

Dose per administration 150

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 (10)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication PANIC ATTACKS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

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

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF CERVICAL
DISC COMPRESSION WITH
RADICULOPATHY

Dose per administration 5-325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 70

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

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 (13)

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

	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)		28 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3152413

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 02:25:18

Generated On: 09 Jun 2021 15:20:38

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 02:25:18

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Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 APR 2021	CHOLECYSTECTOMY	Adverse Event	

US3152413

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:20:38

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:20:38

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 ☐

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

SAEID	USA-US073-2021-MRNA-1273-P301000012
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)	1

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 17:42:47

Generated On: 09 Jun 2021 15:20:38

SAEID	USA-US073-2021-MRNA-1273-P301000012
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)	1
Date of submission (Pre-filled from custom function)	08/APR/2021 18:36
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

US3152413 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

US3152413

Form: Participant Creation

Generated On: 09 Jun 2021 15:20:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'US3152413'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:12:56

US3152413

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 14:22:58

US3152413

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:12:57

US3152413

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	29 Sep 2020 14:22:58

US3152413

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'SCRN'	System	29 Sep 2020 14:22:58

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:12:59

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '48'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'YEARS'	System	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '48'	System	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Female (F)'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'I'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Hispanic'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:20:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 14:29:30

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'Sep 2020'	System	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2020'	System	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Amendment 3 (3)'	Devan Myers (b) (4)	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)' reason for change: Data Entry Error	Devan Myers (b) (4)	29 Sep 2020 14:30:29
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 14:30:18

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	29 Sep 2020 14:30:29
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	29 Sep 2020 14:30:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:12:57

US3152413

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:20:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'I'	System	29 Sep 2020 14:30:49

US3152413

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 14:30:49

US3152413

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:20:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:17:05

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of POLYCYSTIC OVARIAN SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:58:03
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 15:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 15:09:46
Data point term sent to Coder	System	26 Oct 2020 15:03:13
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of POLYCYSTIC OVARIAN SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated accordingly' (Site from DM).	Devan Myers (b) (4)	26 Oct 2020 15:03:07
Coding entries removed.	Devan Myers (b) (4)	26 Oct 2020 15:03:04
User entered 'Bilateral POLYCYSTIC OVARIAN SYNDROME' reason for change: Data Entry Error	Devan Myers (b) (4)	26 Oct 2020 15:03:04
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of POLYCYSTIC OVARIAN SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:01:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:19:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:19:45
Data point term sent to Coder	System	29 Sep 2020 15:18:15
User entered 'Polycystic Ovarian Syndrome'	Devan Myers (b) (4)	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'UN UNK 2010'	Devan Myers (b) (4)	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'Jan 2010'	System	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2010'	System	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:17:39

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:19:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:19:46
Data point term sent to Coder	System	29 Sep 2020 15:18:15
User entered 'Migraines'	Devan Myers (b) (4)	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'UN UNK 2018'	Devan Myers (b) (4)	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'Jan 2018'	System	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2018'	System	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:18:11

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:20:37
Data point term sent to Coder	System	29 Sep 2020 15:19:18
User entered 'Seasonal Allergies'	Devan Myers (b) (4)	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'UN UNK 2000'	Devan Myers (b) (4)	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'Jan 2000'	System	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2000'	System	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:18:36

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:20:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 15:20:38
Data point term sent to Coder	System	29 Sep 2020 15:19:18
User entered 'Acne'	Devan Myers (b) (4)	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'UN UNK 2018'	Devan Myers (b) (4)	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'Jan 2018'	System	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2018'	System	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:18:54

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
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)	23 Feb 2021 18:20:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 18:20:07
Data point term sent to Coder	System	23 Feb 2021 18:19:42
User entered 'anxiety'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:39
	(b) (4)	

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'un UNK 2018'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'Jan 2018'	System	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2018'	System	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	23 Feb 2021 18:19:39

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc compression, LLT: Intervertebral disc compression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:30:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 13:30:39
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
Data point term sent to Coder	System	23 Feb 2021 18:20:44
User entered 'cervical disc compression c5-c6'	Juliana DeVito (b) (4) (b) (4)	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'un May 2019'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'May 2019'	System	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2019'	System	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	23 Feb 2021 18:19:55

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 18:22:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 18:22:03
Data point term sent to Coder	System	23 Feb 2021 18:21:45
User entered 'motor vehicle accident'	Juliana DeVito (b) (4)	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'un May 2019'	Juliana DeVito (b) (4)	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'un May 2019'	Juliana DeVito (b) (4)	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'May 2019'	System	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2019'	System	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'May 2019'	System	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '2019'	System	23 Feb 2021 18:20:48

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '09:08'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '29 Sep 2020 09:08'	System	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '165' cm	Devan Myers (b) (4)	29 Sep 2020 15:20:12
DataPoint set to visible.	(b) (4) System	29 Sep 2020 14:30:49

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '103.7' kg	Devan Myers (b) (4)	29 Sep 2020 15:20:12
DataPoint set to visible.	(b) (4) System	29 Sep 2020 14:30:49

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered '38.08999'	System	29 Sep 2020 15:20:12
DataPoint set to visible.	System	29 Sep 2020 14:30:49

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'kg/m2'	System	29 Sep 2020 15:20:12
DataPoint set to visible.	System	29 Sep 2020 14:30:49

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User closed query 'Per CDM: Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 00:23:42
Query 'Per CDM: Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' answered with 'UPDATED' (Site from DM).	Jemario Blackwell (b) (4)	24 Oct 2020 19:01:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Oct 2020 19:00:56
User opened query 'Per CDM: Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:41:36
User entered '36.1' C	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty; reason for change Data Entry Error	Jemario Blackwell (b) (4)	24 Oct 2020 19:00:56
User entered 'Oral (Oral)'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jemario Blackwell (b) (4)	24 Oct 2020 19:00:56
User entered '88'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'bpm'	System	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jemario Blackwell (b) (4)	24 Oct 2020 19:00:56
User entered '14'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'breaths/min'	System	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jemario Blackwell (b) (4)	24 Oct 2020 19:00:56
User entered '126'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'mmHg'	System	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Jemario Blackwell (b) (4)	24 Oct 2020 19:00:56
User entered '84'	Devan Myers (b) (4)	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered 'mmHg'	System	29 Sep 2020 15:20:12

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41

US3152413

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41

US3152413

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:20:22

US3152413

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:20:22

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:20:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:20:34

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Urine (URINE)'	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Negative (NEGATIVE)'	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User entered empty.	System	29 Sep 2020 15:20:51

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Office work surrounded by multiple employees'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'I'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:20:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:35:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:22:01

US3152413

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:22:27

US3152413

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:22:27

US3152413

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	29 Sep 2020 15:22:27

US3152413

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'VISIT1'	System	29 Sep 2020 15:22:27

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:58:14

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '112768'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:58:14

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Sep 2020 13:58:14

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:24:17

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:24:17

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:24:17

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:24:17

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:24:17

US3152413

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:24:17
DataPoint set to visible.	(b) (4) System	29 Sep 2020 14:30:18

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User accepted default value 'Pre-Dose (PREDOSE)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '09:08'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '29 Sep 2020 09:08'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '36.1' C	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Oral (Oral)'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '88'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'bpm'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '14'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'breaths/min'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '126'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'mmHg'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '84'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'mmHg'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:20:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered missing code ND - Not Done.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User accepted default value 'Post-Dose (POSTDOSE)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '10:48'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '29 Sep 2020 10:48'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '36.8' C	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Oral (Oral)'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '69'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'bpm'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '15'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'breaths/min'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '127'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'mmHg'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '88'	Devan Myers (b) (4)	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'mmHg'	System	29 Sep 2020 15:25:59

US3152413

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:26:06

US3152413

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:26:06

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Urine (URINE)'	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Negative (NEGATIVE)'	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered empty.	System	29 Sep 2020 15:26:19

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '10:18'	Devan Myers (b) (4)	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '29 Sep 2020 10:18'	System	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'ONCE'	System	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:31:42

US3152413

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:26:41

US3152413

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User closed query 'Per GCL Lab Reconciliation Requery 1: Antibody-mediated Immunogenicity: per response, please confirm the visit for which the immuno sample dated 29SEP 2020 belongs.Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 12:49:08
Query 'Per GCL Lab Reconciliation Requery 1: Antibody-mediated Immunogenicity: per response, please confirm the visit for which the immuno sample dated 29SEP 2020 belongs.Thanks ' answered with 'Immuno sample dated 29SEP 2020 belongs to Visit 1. ' (Site from DM).	Priscilla Buahin (b) (4) (b) (4)	21 Dec 2020 19:28:42
User opened query 'Per GCL Lab Reconciliation Requery 1: Antibody-mediated Immunogenicity: per response, please confirm the visit for which the immuno sample dated 29SEP 2020 belongs.Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:54:36
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29 SEP 2020 is recorded under Visit 1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:54:36
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29 SEP 2020 is recorded under Visit 1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Pending resolution from GSS, thanks.' (Site from DM).	Jemario Blackwell (b) (4) (b) (4)	24 Oct 2020 14:52:55
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29 SEP 2020 is recorded under Visit 1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:19:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3152413

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:26:41

US3152413

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '09:47'	Devan Myers (b) (4)	29 Sep 2020 15:26:41

US3152413

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '29 Sep 2020 09:47'	System	29 Sep 2020 15:26:41

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User closed query 'Per GCL Lab Reconciliation: Response to previous query" Pending resolution from GSS, thanks", Swab: Sample dated 29SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm if sample is collected for Visit 1 Day 1 or for UNSCHEDULED visit. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:11:44
Query 'Per GCL Lab Reconciliation: Response to previous query" Pending resolution from GSS, thanks", Swab: Sample dated 29SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm if sample is collected for Visit 1 Day 1 or for UNSCHEDULED visit. Else Clarify, Thank you.' answered with 'Confirmed. Swab sample dated 29-SEP-2020 is collected for Visit 1 Day 1.' (Site from DM).	Priscilla Buahin (b) (4)	21 Dec 2020 19:30:06
User opened query 'Per GCL Lab Reconciliation: Response to previous query" Pending resolution from GSS, thanks", Swab: Sample dated 29SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm if sample is collected for Visit 1 Day 1 or for UNSCHEDULED visit. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 09:11:58
User closed query 'Per CDM RQ : Response Noted. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:08:52
Query 'Per CDM RQ : Response Noted. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you ' answered with 'correct visit date. ' (Site from DM).	Jemario Blackwell (b) (4)	03 Nov 2020 21:37:26
User opened query 'Per CDM RQ : Response Noted. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:36:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:20:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 29 SEP 2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:36:36
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 29 SEP 2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' answered with 'Pending resolution from GSS, thanks.' (Site from DM).	Jemario Blackwell (b) (4)	24 Oct 2020 15:19:31
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 29 SEP 2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:28:06
User entered '29 Sep 2020'	Devan Myers (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '09:40'	Devan Myers (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '29 Sep 2020 09:40'	System	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered empty.	System	29 Sep 2020 15:27:04

US3152413

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:27:09

US3152413

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	29 Sep 2020 15:27:09

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:51:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4d7abbb3-271d-4a9a-8863-60c7559d08c5' User entered 'Yes (Y)'	System	29 Sep 2020 14:51:48
	System	29 Sep 2020 14:51:48

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:51:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4d7abbb3-271d-4a9a-8863-60c7559d08c5' User entered '98.2'	System	29 Sep 2020 14:51:48
	System	29 Sep 2020 14:51:48

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:51:42', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4d7abbb3-271d-4a9a-8863-60c7559d08c5'	System	29 Sep 2020 14:51:48
User entered 'No (N)'	System	29 Sep 2020 14:51:48

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:51:46', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4d7abbb3-271d-4a9a-8863-60c7559d08c5' User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:48
	System	29 Sep 2020 14:51:48

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 10:38'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 13:08'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:36:12', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0f3cdf87-2d1e-4da4-973b-01ea9ef09544'	System	29 Sep 2020 19:36:25
User entered 'Yes (Y)'	System	29 Sep 2020 19:36:25

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:36:17', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0f3cdf87-2d1e-4da4-973b-01ea9ef09544' User entered '97.9'	System	29 Sep 2020 19:36:25
	System	29 Sep 2020 19:36:25

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:36:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0f3cdf87-2d1e-4da4-973b-01ea9ef09544'	System	29 Sep 2020 19:36:25
User entered 'No (N)'	System	29 Sep 2020 19:36:25

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:36:24', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0f3cdf87-2d1e-4da4-973b-01ea9ef09544'	System	29 Sep 2020 19:36:25
User entered '29 Sep 2020 15:36'	System	29 Sep 2020 19:36:25

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 14:03'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 2'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:31:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '984a678f-58d0-4402-ba44-5e79ab46102d' User entered 'Yes (Y)'	System	30 Sep 2020 17:32:24
	System	30 Sep 2020 17:32:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:31:57', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '984a678f-58d0-4402-ba44-5e79ab46102d' User entered '98.3'	System	30 Sep 2020 17:32:24
	System	30 Sep 2020 17:32:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:32:01', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '984a678f-58d0-4402-ba44-5e79ab46102d' User entered 'No (N)'	System	30 Sep 2020 17:32:24
	System	30 Sep 2020 17:32:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:32:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '984a678f-58d0-4402-ba44-5e79ab46102d' User entered '30 Sep 2020 13:32'	System	30 Sep 2020 17:32:24
	System	30 Sep 2020 17:32:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 3'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:18', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '7894a9df-1ebf-4d04-bf65-39e1731b3dde' User entered 'Yes (Y)'	System	01 Oct 2020 18:18:35
	System	01 Oct 2020 18:18:35

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:22', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '7894a9df-1ebf-4d04-bf65-39e1731b3dde' User entered '97.9'	System	01 Oct 2020 18:18:35
	System	01 Oct 2020 18:18:35

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:27', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '7894a9df-1ebf-4d04-bf65-39e1731b3dde'	System	01 Oct 2020 18:18:35
User entered 'No (N)'	System	01 Oct 2020 18:18:35

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '7894a9df-1ebf-4d04-bf65-39e1731b3dde' User entered '01 Oct 2020 14:18'	System	01 Oct 2020 18:18:35
	System	01 Oct 2020 18:18:35

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 4'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:50:17', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9f750d5b-65be-4b65-8e73-c36ad5217e2f' User entered 'Yes (Y)'	System	02 Oct 2020 16:50:28
	System	02 Oct 2020 16:50:28

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:50:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9f750d5b-65be-4b65-8e73-c36ad5217e2f' User entered '98.5'	System	02 Oct 2020 16:50:28
	System	02 Oct 2020 16:50:28

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:50:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9f750d5b-65be-4b65-8e73-c36ad5217e2f' User entered 'No (N)'	System	02 Oct 2020 16:50:28
	System	02 Oct 2020 16:50:28

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:50:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9f750d5b-65be-4b65-8e73-c36ad5217e2f' User entered '02 Oct 2020 12:50'	System	02 Oct 2020 16:50:28
	System	02 Oct 2020 16:50:28

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 5'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:26:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bfcc2abc-dae-44dc-8634-1f9720be9411' User entered 'Yes (Y)'	System	03 Oct 2020 17:26:24
	System	03 Oct 2020 17:26:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:26:16', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bfcc2abc-dae-44dc-8634-1f9720be9411' User entered '97.9'	System	03 Oct 2020 17:26:24
	System	03 Oct 2020 17:26:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:26:19', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bfcc2abc-dae-44dc-8634-1f9720be9411'	System	03 Oct 2020 17:26:24
User entered 'No (N)'	System	03 Oct 2020 17:26:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:26:21', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bfcc2abc-dae-44dc-8634-1f9720be9411' User entered '03 Oct 2020 13:26'	System	03 Oct 2020 17:26:24
	System	03 Oct 2020 17:26:24

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 6'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:03:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8be997f1-0cac-4ba0-af65-f13e24c297b6' User entered 'Yes (Y)'	System	04 Oct 2020 16:03:38
	System	04 Oct 2020 16:03:38

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:03:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8be997f1-0cac-4ba0-af65-f13e24c297b6' User entered '97.3'	System	04 Oct 2020 16:03:38
	System	04 Oct 2020 16:03:38

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:03:32', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8be997f1-0cac-4ba0-af65-f13e24c297b6'	System	04 Oct 2020 16:03:38
User entered 'No (N)'	System	04 Oct 2020 16:03:38

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:03:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8be997f1-0cac-4ba0-af65-f13e24c297b6' User entered '04 Oct 2020 12:03'	System	04 Oct 2020 16:03:38
	System	04 Oct 2020 16:03:38

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 7'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:53:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '482864ff-041a-4d02-a788-cfa85ac545ba' User entered 'Yes (Y)'	System	05 Oct 2020 21:53:53
	System	05 Oct 2020 21:53:53

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:53:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '482864ff-041a-4d02-a788-cfa85ac545ba' User entered '98.9'	System	05 Oct 2020 21:53:53
	System	05 Oct 2020 21:53:53

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:53:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '482864ff-041a-4d02-a788-cfa85ac545ba' User entered 'No (N)'	System	05 Oct 2020 21:53:53
	System	05 Oct 2020 21:53:53

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:53:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '482864ff-041a-4d02-a788-cfa85ac545ba' User entered '05 Oct 2020 17:53'	System	05 Oct 2020 21:53:53
	System	05 Oct 2020 21:53:53

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:49:48', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64ed64d4-129e-466a-966b-fe3f958a780c' User entered 'None (1)'	System	29 Sep 2020 14:50:48
	System	29 Sep 2020 14:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64ed64d4-129e-466a-966b-fe3f958a780c' User entered 'No (N)'	System	29 Sep 2020 14:50:48
	System	29 Sep 2020 14:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64ed64d4-129e-466a-966b-fe3f958a780c' User entered 'No (N)'	System	29 Sep 2020 14:50:48
	System	29 Sep 2020 14:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:19', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64ed64d4-129e-466a-966b-fe3f958a780c' User entered 'None (1)'	System	29 Sep 2020 14:50:48
	System	29 Sep 2020 14:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:26', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64ed64d4-129e-466a-966b-fe3f958a780c' User entered '29 Sep 2020 10:50'	System	29 Sep 2020 14:50:48
	System	29 Sep 2020 14:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 10:38'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 13:08'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2fdf9b6c-699a-472d-b27a-230aef002483'	System	29 Sep 2020 19:29:18
User entered 'None (1)'	System	29 Sep 2020 19:29:18

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:27:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2fdf9b6c-699a-472d-b27a-230aef002483' User entered 'Yes (Y)'	System	29 Sep 2020 19:29:18
	System	29 Sep 2020 19:29:18

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:28:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2fdf9b6c-699a-472d-b27a-230aef002483' User entered '30'	System	29 Sep 2020 19:29:18
	System	29 Sep 2020 19:29:18

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:28:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2fdf9b6c-699a-472d-b27a-230aef002483'	System	29 Sep 2020 19:29:18
User entered 'No (N)'	System	29 Sep 2020 19:29:18

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2fdf9b6c-699a-472d-b27a-230aef002483'	System	29 Sep 2020 19:29:18
User entered 'None (1)'	System	29 Sep 2020 19:29:18

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:15', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2fdf9b6c-699a-472d-b27a-230aef002483' User entered '29 Sep 2020 15:29'	System	29 Sep 2020 19:29:18
	System	29 Sep 2020 19:29:18

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 14:03'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 2'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:26:36', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4a584473-9386-42d4-bade-c0728034cf86'	System	30 Sep 2020 17:27:38
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 17:27:38

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:26:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4a584473-9386-42d4-bade-c0728034cf86' User entered 'Yes (Y)'	System	30 Sep 2020 17:27:38
	System	30 Sep 2020 17:27:38

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:26:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4a584473-9386-42d4-bade-c0728034cf86' User entered '30'	System	30 Sep 2020 17:27:38
	System	30 Sep 2020 17:27:38

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:27:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4a584473-9386-42d4-bade-c0728034cf86' User entered 'No (N)'	System	30 Sep 2020 17:27:38
	System	30 Sep 2020 17:27:38

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:27:27', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4a584473-9386-42d4-bade-c0728034cf86' User entered 'None (1)'	System	30 Sep 2020 17:27:38
	System	30 Sep 2020 17:27:38

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:27:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4a584473-9386-42d4-bade-c0728034cf86' User entered '30 Sep 2020 13:27'	System	30 Sep 2020 17:27:38
	System	30 Sep 2020 17:27:38

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 3'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6'	System	01 Oct 2020 18:19:16
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:40', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6' User entered 'Yes (Y)'	System	01 Oct 2020 18:19:16
	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6' User entered '35'	System	01 Oct 2020 18:19:16
	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:18:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6' User entered 'Yes (Y)'	System	01 Oct 2020 18:19:16
	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6' User entered '1'	System	01 Oct 2020 18:19:16
	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6'	System	01 Oct 2020 18:19:16
User entered 'None (1)'	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'be9b863b-232c-4ac7-bf47-500315451fd6'	System	01 Oct 2020 18:19:16
User entered '01 Oct 2020 14:19'	System	01 Oct 2020 18:19:16

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 4'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:46:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bba40e42-1eb1-42b9-ab49-f1c622940a06' User entered 'None (1)'	System	02 Oct 2020 16:47:28
	System	02 Oct 2020 16:47:28

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:46:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bba40e42-1eb1-42b9-ab49-f1c622940a06'	System	02 Oct 2020 16:47:28
User entered 'Yes (Y)'	System	02 Oct 2020 16:47:28

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bba40e42-1eb1-42b9-ab49-f1c622940a06' User entered '28'	System	02 Oct 2020 16:47:28
	System	02 Oct 2020 16:47:28

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bba40e42-1eb1-42b9-ab49-f1c622940a06' User entered 'No (N)'	System	02 Oct 2020 16:47:28
	System	02 Oct 2020 16:47:28

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:11', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bba40e42-1eb1-42b9-ab49-f1c622940a06' User entered 'None (1)'	System	02 Oct 2020 16:47:28
	System	02 Oct 2020 16:47:28

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'bba40e42-1eb1-42b9-ab49-f1c622940a06' User entered '02 Oct 2020 12:47'	System	02 Oct 2020 16:47:28
	System	02 Oct 2020 16:47:28

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 5'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3750f99b-bbbe-4622-8958-f69f5d296e27'	System	03 Oct 2020 17:23:30
User entered 'None (1)'	System	03 Oct 2020 17:23:30

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:05', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3750f99b-bbbe-4622-8958-f69f5d296e27'	System	03 Oct 2020 17:23:30
User entered 'Yes (Y)'	System	03 Oct 2020 17:23:30

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3750f99b-bbbe-4622-8958-f69f5d296e27' User entered '10'	System	03 Oct 2020 17:23:30
	System	03 Oct 2020 17:23:30

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:10', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3750f99b-bbbe-4622-8958-f69f5d296e27'	System	03 Oct 2020 17:23:30
User entered 'No (N)'	System	03 Oct 2020 17:23:30

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3750f99b-bbbe-4622-8958-f69f5d296e27'	System	03 Oct 2020 17:23:30
User entered 'None (1)'	System	03 Oct 2020 17:23:30

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:15', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3750f99b-bbbe-4622-8958-f69f5d296e27' User entered '03 Oct 2020 13:23'	System	03 Oct 2020 17:23:30
	System	03 Oct 2020 17:23:30

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 6'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ffdbae37-8818-48db-89ba-0db6ea7ecf80'	System	04 Oct 2020 16:01:19
User entered 'None (1)'	System	04 Oct 2020 16:01:19

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:54', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ffdbae37-8818-48db-89ba-0db6ea7ecf80'	System	04 Oct 2020 16:01:19
User entered 'No (N)'	System	04 Oct 2020 16:01:19

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ffdbae37-8818-48db-89ba-0db6ea7ecf80' User entered 'No (N)'	System	04 Oct 2020 16:01:19
	System	04 Oct 2020 16:01:19

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:58', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ffdbae37-8818-48db-89ba-0db6ea7ecf80'	System	04 Oct 2020 16:01:19
User entered 'None (1)'	System	04 Oct 2020 16:01:19

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:01:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ffdbae37-8818-48db-89ba-0db6ea7ecf80' User entered '04 Oct 2020 12:01'	System	04 Oct 2020 16:01:19
	System	04 Oct 2020 16:01:19

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 7'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '458f1e0c-bf75-4d2c-8b72-5ea7ec5623df' User entered 'None (1)'	System	05 Oct 2020 21:50:48
	System	05 Oct 2020 21:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '458f1e0c-bf75-4d2c-8b72-5ea7ec5623df' User entered 'No (N)'	System	05 Oct 2020 21:50:48
	System	05 Oct 2020 21:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:39', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '458f1e0c-bf75-4d2c-8b72-5ea7ec5623df' User entered 'No (N)'	System	05 Oct 2020 21:50:48
	System	05 Oct 2020 21:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:42', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '458f1e0c-bf75-4d2c-8b72-5ea7ec5623df' User entered 'None (1)'	System	05 Oct 2020 21:50:48
	System	05 Oct 2020 21:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:45', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '458f1e0c-bf75-4d2c-8b72-5ea7ec5623df' User entered '05 Oct 2020 17:50'	System	05 Oct 2020 21:50:48
	System	05 Oct 2020 21:50:48

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'None (0)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'None (0)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'None (0)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'None (0)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'None (0)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'None (0)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:50:58', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered 'No (N)'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T10:51:03', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd72d155b-5d84-4fd2-959d-3b840d259a7f' User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:06
	System	29 Sep 2020 14:51:06

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 10:38'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 13:08'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:24', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'None (0)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'None (0)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:33', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'None (0)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'None (0)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'None (0)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:39', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'None (0)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered 'No (N)'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-29T15:29:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '71aac1fb-93f1-4bdb-9498-915e8c777d31' User entered '29 Sep 2020 15:29'	System	29 Sep 2020 19:29:49
	System	29 Sep 2020 19:29:49

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Sep 2020 14:03'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 2'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:27:43', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'None (0)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:27:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'None (0)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:27:54', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'No interference with activity (1)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:28:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'None (0)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:28:06', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'None (0)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:28:09', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'None (0)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:28:15', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered 'No (N)'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-09-30T13:28:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e840c72e-2a9c-441f-a3e6-c307b40cebf1' User entered '30 Sep 2020 13:28'	System	30 Sep 2020 17:28:22
	System	30 Sep 2020 17:28:22

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 3'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c' User entered 'None (0)'	System	01 Oct 2020 18:19:40
	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c' User entered 'None (0)'	System	01 Oct 2020 18:19:40
	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:26', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c'	System	01 Oct 2020 18:19:40
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c'	System	01 Oct 2020 18:19:40
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:31', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c' User entered 'None (0)'	System	01 Oct 2020 18:19:40
	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:33', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c' User entered 'None (0)'	System	01 Oct 2020 18:19:40
	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:36', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c' User entered 'No (N)'	System	01 Oct 2020 18:19:40
	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-01T14:19:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0449c51b-4526-4b43-a918-bf105441c65c' User entered '01 Oct 2020 14:19'	System	01 Oct 2020 18:19:40
	System	01 Oct 2020 18:19:40

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 4'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:33', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'None (0)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'None (0)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'None (0)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:40', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'None (0)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:42', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'None (0)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'None (0)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered 'No (N)'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-02T12:47:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0e007f35-6c65-4be3-8cac-175dba8ed177' User entered '02 Oct 2020 12:47'	System	02 Oct 2020 16:47:51
	System	02 Oct 2020 16:47:51

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 5'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:21', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'None (0)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'None (0)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:26', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'None (0)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'None (0)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:31', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'None (0)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:33', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'None (0)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered 'No (N)'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-03T13:23:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33cfed67-18a1-4963-9c0f-2d342fdb2210' User entered '03 Oct 2020 13:23'	System	03 Oct 2020 17:23:43
	System	03 Oct 2020 17:23:43

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 6'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:31', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered 'None (0)'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered 'None (0)'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:36', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered 'None (0)'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered 'None (0)'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:39', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered 'None (0)'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered 'None (0)'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:43', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90'	System	04 Oct 2020 16:00:55
User entered 'No (N)'	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-04T12:00:46', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c27ed1ca-e1ec-4a05-a476-aac8062f4b90' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 16:00:55
	System	04 Oct 2020 16:00:55

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	29 Sep 2020 14:31:42
User entered 'Day 7'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:51', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d'	System	05 Oct 2020 21:51:11
User entered 'No interference with activity (1)'	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered 'None (0)'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:55', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered 'None (0)'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:57', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered 'None (0)'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:50:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered 'None (0)'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:51:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered 'None (0)'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:51:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered 'No (N)'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-05T17:51:06', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'e5f18bc4-1ce0-4040-88c7-9baaea645d3d' User entered '05 Oct 2020 17:51'	System	05 Oct 2020 21:51:11
	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:31:42

US3152413

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	05 Oct 2020 21:51:11
User entered 'Day 8'	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-06T18:35:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '6905afaf-8d64-4bdc-8ae5-25b195fadf72' User entered 'None (0)'	System	06 Oct 2020 22:35:37
	System	06 Oct 2020 22:35:37

US3152413

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-06T18:35:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '6905afaf-8d64-4bdc-8ae5-25b195fadf72' User entered '06 Oct 2020 18:35'	System	06 Oct 2020 22:35:37
	System	06 Oct 2020 22:35:37

US3152413

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	05 Oct 2020 21:51:11
User entered 'Day 8'	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-06T18:35:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'acea886e-ce01-4436-a3b0-8d04be3f117b' User entered 'No (N)'	System	06 Oct 2020 22:35:39
	System	06 Oct 2020 22:35:39

US3152413

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-06T18:35:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'acea886e-ce01-4436-a3b0-8d04be3f117b' User entered '06 Oct 2020 18:35'	System	06 Oct 2020 22:35:39
	System	06 Oct 2020 22:35:39

US3152413

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 21:51:11

US3152413

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 21:51:11

US3152413

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:03:23

US3152413

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '06 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:03:23

US3152413

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 21:03:23

US3152413

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:03:23

US3152413

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:03:28

US3152413

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	20 Oct 2020 21:03:28

US3152413

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:03:40

US3152413

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '13 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:03:40

US3152413

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 21:03:40

US3152413

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:03:40

US3152413

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:03:44

US3152413

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	20 Oct 2020 21:03:44

US3152413

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:03:53

US3152413

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:03:53

US3152413

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 21:03:53

US3152413

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:03:53

US3152413

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:03:55

US3152413

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	20 Oct 2020 21:03:55

US3152413

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 12:24:51
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' answered with 'Accession number - 1F60LDL' (Site from DM).	Priscilla Buahin (b) (4)	21 Dec 2020 19:26:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:52:51
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 19:04:39

US3152413

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	27 Oct 2020 19:04:39

US3152413

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Clinic (Clinic)'	Devan Myers (b) (4)	27 Oct 2020 19:04:39

US3152413

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'VISIT2'	System	27 Oct 2020 19:04:39

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User accepted default value 'Pre-Dose (PREDOSE)'	Devan Myers (b) (4) (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '13:30'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered '27 Oct 2020 13:30'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '36.5' C	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Oral (Oral)'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '70'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'bpm'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '15'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'breaths/min'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '110'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'mmHg'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '81'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'mmHg'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User accepted default value 'Post-Dose (POSTDOSE)'	Devan Myers (b) (4) (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '15:07'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered '27 Oct 2020 15:07'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '36.9' C	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Oral (Oral)'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '70'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'bpm'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '15'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'breaths/min'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '129'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'mmHg'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '85'	Devan Myers (b) (4)	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'mmHg'	System	03 Nov 2020 21:43:13

US3152413

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 19:04:46

US3152413

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	27 Oct 2020 19:04:46

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Urine (URINE)'	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Negative (NEGATIVE)'	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered empty.	System	27 Oct 2020 19:04:57

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '14:37' reason for change: Data Entry Error	Devan Myers (b) (4)	27 Oct 2020 19:08:33
User entered '15:37'	Devan Myers (b) (4)	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '27 Oct 2020 14:37'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 15:37'	System	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'ONCE'	System	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:20:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 18:52:44

US3152413

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 19:05:21

US3152413

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	27 Oct 2020 19:05:21

US3152413

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '13:34'	Devan Myers (b) (4)	27 Oct 2020 19:05:21

US3152413

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '27 Oct 2020 13:34'	System	27 Oct 2020 19:05:21

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '27 Oct 2020'	Devan Myers (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Devan Myers (b) (4) (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '14:33'	Devan Myers (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered '27 Oct 2020 14:33'	System	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Devan Myers (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Devan Myers (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered empty.	System	27 Oct 2020 19:05:34

US3152413

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	27 Oct 2020 19:05:40

US3152413

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	27 Oct 2020 19:05:40

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '53d8adf2-b374-41e0-9b8a-b0f92ace3afd' User entered 'Yes (Y)'	System	27 Oct 2020 19:10:16
	System	27 Oct 2020 19:10:16

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:10:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '53d8adf2-b374-41e0-9b8a-b0f92ace3afd' User entered '98.3'	System	27 Oct 2020 19:10:16
	System	27 Oct 2020 19:10:16

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:10:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '53d8adf2-b374-41e0-9b8a-b0f92ace3afd'	System	27 Oct 2020 19:10:16
User entered 'No (N)'	System	27 Oct 2020 19:10:16

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:10:10', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '53d8adf2-b374-41e0-9b8a-b0f92ace3afd' User entered '27 Oct 2020 15:10'	System	27 Oct 2020 19:10:16
	System	27 Oct 2020 19:10:16

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 14:57'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 15:57'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 17:27'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 18:27'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:28:54', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '24c450d7-4488-4d3c-9410-9be00945a003' User entered 'Yes (Y)'	System	27 Oct 2020 22:29:07
	System	27 Oct 2020 22:29:07

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:28:57', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '24c450d7-4488-4d3c-9410-9be00945a003' User entered '97.6'	System	27 Oct 2020 22:29:07
	System	27 Oct 2020 22:29:07

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '24c450d7-4488-4d3c-9410-9be00945a003'	System	27 Oct 2020 22:29:07
User entered 'No (N)'	System	27 Oct 2020 22:29:07

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:03', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '24c450d7-4488-4d3c-9410-9be00945a003'	System	27 Oct 2020 22:29:07
User entered '27 Oct 2020 18:29'	System	27 Oct 2020 22:29:07

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 18:22'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 19:22'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 2'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:11', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9a92531e-c983-4142-a5e0-21620d11ebcc' User entered 'Yes (Y)'	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:14', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9a92531e-c983-4142-a5e0-21620d11ebcc' User entered '97.6'	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:18', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9a92531e-c983-4142-a5e0-21620d11ebcc' User entered 'Yes (Y)'	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been contacted and medication recorded in Con Med list' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:38:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Devan Myers (b) (4)	04 Nov 2020 13:55:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9a92531e-c983-4142-a5e0-21620d11ebcc'	(b) (4)	
User entered '1'	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9a92531e-c983-4142-a5e0-21620d11ebcc' User entered '0'	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:32', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9a92531e-c983-4142-a5e0-21620d11ebcc' User entered '28 Oct 2020 12:45'	System	28 Oct 2020 16:45:38
	System	28 Oct 2020 16:45:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 3'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:43', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9fa5b9eb-8f75-4e09-ba5a-810a54267b65' User entered 'Yes (Y)'	System	29 Oct 2020 21:37:55
	System	29 Oct 2020 21:37:55

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9fa5b9eb-8f75-4e09-ba5a-810a54267b65' User entered '98.6'	System	29 Oct 2020 21:37:55
	System	29 Oct 2020 21:37:55

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9fa5b9eb-8f75-4e09-ba5a-810a54267b65'	System	29 Oct 2020 21:37:55
User entered 'No (N)'	System	29 Oct 2020 21:37:55

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:52', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9fa5b9eb-8f75-4e09-ba5a-810a54267b65' User entered '29 Oct 2020 17:37'	System	29 Oct 2020 21:37:55
	System	29 Oct 2020 21:37:55

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 4'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:06', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c8f6d8b2-8429-4789-bfed-35917c1ab62a' User entered 'Yes (Y)'	System	30 Oct 2020 16:46:18
	System	30 Oct 2020 16:46:18

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:09', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c8f6d8b2-8429-4789-bfed-35917c1ab62a' User entered '97.6'	System	30 Oct 2020 16:46:18
	System	30 Oct 2020 16:46:18

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:12', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c8f6d8b2-8429-4789-bfed-35917c1ab62a'	System	30 Oct 2020 16:46:18
User entered 'No (N)'	System	30 Oct 2020 16:46:18

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:14', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c8f6d8b2-8429-4789-bfed-35917c1ab62a' User entered '30 Oct 2020 12:46'	System	30 Oct 2020 16:46:18
	System	30 Oct 2020 16:46:18

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 5'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64936d0b-27e9-4df3-95a9-d2fc310ed911' User entered 'Yes (Y)'	System	31 Oct 2020 18:18:38
	System	31 Oct 2020 18:18:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:27', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64936d0b-27e9-4df3-95a9-d2fc310ed911' User entered '97.7'	System	31 Oct 2020 18:18:38
	System	31 Oct 2020 18:18:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64936d0b-27e9-4df3-95a9-d2fc310ed911' User entered 'No (N)'	System	31 Oct 2020 18:18:38
	System	31 Oct 2020 18:18:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:33', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '64936d0b-27e9-4df3-95a9-d2fc310ed911' User entered '31 Oct 2020 14:18'	System	31 Oct 2020 18:18:38
	System	31 Oct 2020 18:18:38

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 6'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '202c8e23-6451-4005-8bc5-39b1e0d3f906' User entered 'Yes (Y)'	System	01 Nov 2020 18:24:25
	System	01 Nov 2020 18:24:25

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:09', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '202c8e23-6451-4005-8bc5-39b1e0d3f906' User entered '97.7'	System	01 Nov 2020 18:24:25
	System	01 Nov 2020 18:24:25

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '202c8e23-6451-4005-8bc5-39b1e0d3f906' User entered 'No (N)'	System	01 Nov 2020 18:24:25
	System	01 Nov 2020 18:24:25

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:22', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '202c8e23-6451-4005-8bc5-39b1e0d3f906' User entered '01 Nov 2020 13:24'	System	01 Nov 2020 18:24:25
	System	01 Nov 2020 18:24:25

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 7'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33fdc302-65b9-40a6-84ac-c1443298d6e9' User entered 'Yes (Y)'	System	02 Nov 2020 17:48:34
	System	02 Nov 2020 17:48:34

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:26', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33fdc302-65b9-40a6-84ac-c1443298d6e9' User entered '97.7'	System	02 Nov 2020 17:48:34
	System	02 Nov 2020 17:48:34

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33fdc302-65b9-40a6-84ac-c1443298d6e9' User entered 'No (N)'	System	02 Nov 2020 17:48:34
	System	02 Nov 2020 17:48:34

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '33fdc302-65b9-40a6-84ac-c1443298d6e9' User entered '02 Nov 2020 12:48'	System	02 Nov 2020 17:48:34
	System	02 Nov 2020 17:48:34

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:08:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd6d194f0-fd50-493c-8bbb-dedaae6e39f3'	System	27 Oct 2020 19:09:06
User entered 'None (1)'	System	27 Oct 2020 19:09:06

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:08:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd6d194f0-fd50-493c-8bbb-dedaae6e39f3'	System	27 Oct 2020 19:09:06
User entered 'No (N)'	System	27 Oct 2020 19:09:06

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:08:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd6d194f0-fd50-493c-8bbb-dedaae6e39f3'	System	27 Oct 2020 19:09:06
User entered 'No (N)'	System	27 Oct 2020 19:09:06

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:08:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd6d194f0-fd50-493c-8bbb-dedaae6e39f3'	System	27 Oct 2020 19:09:06
User entered 'None (1)'	System	27 Oct 2020 19:09:06

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd6d194f0-fd50-493c-8bbb-dedaae6e39f3' User entered '27 Oct 2020 15:09'	System	27 Oct 2020 19:09:06
	System	27 Oct 2020 19:09:06

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 14:57'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 15:57'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 17:27'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 18:27'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9de4aefa-63af-4ff0-a08f-7d876cb69f52'	System	27 Oct 2020 22:29:20
User entered 'None (1)'	System	27 Oct 2020 22:29:20

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:10', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9de4aefa-63af-4ff0-a08f-7d876cb69f52'	System	27 Oct 2020 22:29:20
User entered 'No (N)'	System	27 Oct 2020 22:29:20

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:12', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9de4aefa-63af-4ff0-a08f-7d876cb69f52'	System	27 Oct 2020 22:29:20
User entered 'No (N)'	System	27 Oct 2020 22:29:20

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:14', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9de4aefa-63af-4ff0-a08f-7d876cb69f52'	System	27 Oct 2020 22:29:20
User entered 'None (1)'	System	27 Oct 2020 22:29:20

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:17', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9de4aefa-63af-4ff0-a08f-7d876cb69f52'	System	27 Oct 2020 22:29:20
User entered '27 Oct 2020 18:29'	System	27 Oct 2020 22:29:20

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 18:22'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 19:22'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 2'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:45', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7'	System	28 Oct 2020 16:46:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:45:52', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7'	System	28 Oct 2020 16:46:49
User entered 'Yes (Y)'	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7' User entered '65'	System	28 Oct 2020 16:46:49
	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7'	System	28 Oct 2020 16:46:49
User entered 'Yes (Y)'	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:40', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7' User entered '65'	System	28 Oct 2020 16:46:49
	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:43', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7'	System	28 Oct 2020 16:46:49
User entered 'None (1)'	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:46', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b121763f-c0d7-4262-945f-f99d4b0cd2d7' User entered '28 Oct 2020 12:46'	System	28 Oct 2020 16:46:49
	System	28 Oct 2020 16:46:49

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 3'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:35:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5'	System	29 Oct 2020 21:37:11
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:35:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5'	System	29 Oct 2020 21:37:11
User entered 'Yes (Y)'	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:35:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5' User entered '63'	System	29 Oct 2020 21:37:11
	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:35:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5'	System	29 Oct 2020 21:37:11
User entered 'Yes (Y)'	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:36:39', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5' User entered '4'	System	29 Oct 2020 21:37:11
	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:36:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5'	System	29 Oct 2020 21:37:11
User entered 'None (1)'	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:05', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2950ff71-d2ca-4a28-8302-7f0236b82ad5' User entered '29 Oct 2020 17:37'	System	29 Oct 2020 21:37:11
	System	29 Oct 2020 21:37:11

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 4'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:19', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:21', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered 'Yes (Y)'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered '60'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered 'Yes (Y)'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered '60'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:45', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:48', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1e8cce5d-a6dd-4657-8b02-2f486a958d2b' User entered '30 Oct 2020 12:46'	System	30 Oct 2020 16:46:55
	System	30 Oct 2020 16:46:55

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 5'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:20:17', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a55706bc-b9c6-4337-a8f6-aebf97e92d9c'	System	31 Oct 2020 18:20:38
User entered 'None (1)'	System	31 Oct 2020 18:20:38

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:20:19', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a55706bc-b9c6-4337-a8f6-aebf97e92d9c' User entered 'Yes (Y)'	System	31 Oct 2020 18:20:38
	System	31 Oct 2020 18:20:38

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:20:22', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a55706bc-b9c6-4337-a8f6-aebf97e92d9c' User entered '30'	System	31 Oct 2020 18:20:38
	System	31 Oct 2020 18:20:38

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:20:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a55706bc-b9c6-4337-a8f6-aebf97e92d9c' User entered 'No (N)'	System	31 Oct 2020 18:20:38
	System	31 Oct 2020 18:20:38

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:20:32', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a55706bc-b9c6-4337-a8f6-aebf97e92d9c'	System	31 Oct 2020 18:20:38
User entered 'None (1)'	System	31 Oct 2020 18:20:38

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:20:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a55706bc-b9c6-4337-a8f6-aebf97e92d9c' User entered '31 Oct 2020 14:20'	System	31 Oct 2020 18:20:38
	System	31 Oct 2020 18:20:38

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 6'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b5e7e541-b907-4473-ac15-0e6bb5756714' User entered 'None (1)'	System	01 Nov 2020 18:25:10
	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b5e7e541-b907-4473-ac15-0e6bb5756714' User entered 'Yes (Y)'	System	01 Nov 2020 18:25:10
	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b5e7e541-b907-4473-ac15-0e6bb5756714' User entered '40'	System	01 Nov 2020 18:25:10
	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b5e7e541-b907-4473-ac15-0e6bb5756714' User entered 'No (N)'	System	01 Nov 2020 18:25:10
	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:24:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b5e7e541-b907-4473-ac15-0e6bb5756714' User entered 'None (1)'	System	01 Nov 2020 18:25:10
	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'b5e7e541-b907-4473-ac15-0e6bb5756714' User entered '01 Nov 2020 13:25'	System	01 Nov 2020 18:25:10
	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 7'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '68ea7277-6212-4cee-9594-3be7865c1e5b' User entered 'None (1)'	System	02 Nov 2020 17:48:50
	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '68ea7277-6212-4cee-9594-3be7865c1e5b' User entered 'Yes (Y)'	System	02 Nov 2020 17:48:50
	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:40', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '68ea7277-6212-4cee-9594-3be7865c1e5b' User entered '30'	System	02 Nov 2020 17:48:50
	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:42', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '68ea7277-6212-4cee-9594-3be7865c1e5b' User entered 'No (N)'	System	02 Nov 2020 17:48:50
	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:44', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '68ea7277-6212-4cee-9594-3be7865c1e5b' User entered 'None (1)'	System	02 Nov 2020 17:48:50
	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '68ea7277-6212-4cee-9594-3be7865c1e5b' User entered '02 Nov 2020 12:48'	System	02 Nov 2020 17:48:50
	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'None (0)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:10', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'None (0)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'None (0)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:15', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'None (0)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:17', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'None (0)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:19', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'None (0)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:24', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered 'No (N)'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T15:09:27', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd5d54207-cbd0-4fef-afdf-5c55bb53c069' User entered '27 Oct 2020 15:09'	System	27 Oct 2020 19:09:32
	System	27 Oct 2020 19:09:32

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 14:57'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 15:57'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 17:27'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 18:27'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:21', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'None (0)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'None (0)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'None (0)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'None (0)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:32', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'None (0)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'None (0)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:37', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered 'No (N)'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-27T18:29:39', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '16805dc0-af69-4fa7-9510-d1fdd7978879' User entered '27 Oct 2020 18:29'	System	27 Oct 2020 22:29:41
	System	27 Oct 2020 22:29:41

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '27 Oct 2020 18:22'	System	27 Oct 2020 19:08:33
User entered '27 Oct 2020 19:22'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 2'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f'	System	28 Oct 2020 16:47:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered 'Some interference with activity (2)'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:46:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered 'Some interference with activity (2)'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:47:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered 'No interference with activity (1)'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:47:05', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered 'None (0)'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:47:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered 'None (0)'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:47:10', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered 'No (N)'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-28T12:47:18', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2a42a441-0c79-4517-9fa7-7d015d69578f' User entered '28 Oct 2020 12:47'	System	28 Oct 2020 16:47:23
	System	28 Oct 2020 16:47:23

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 3'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:11', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered 'None (0)'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:14', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered 'None (0)'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:16', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36'	System	29 Oct 2020 21:37:37
User entered 'No interference with activity (1)'	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:18', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered 'None (0)'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:21', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered 'None (0)'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:27', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered 'None (0)'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:30', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered 'No (N)'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-29T17:37:34', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3486987c-2cd4-43bd-92e5-246a8ff97b36' User entered '29 Oct 2020 17:37'	System	29 Oct 2020 21:37:37
	System	29 Oct 2020 21:37:37

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 4'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'None (0)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:46:57', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'None (0)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:47:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'None (0)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:47:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'None (0)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:47:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'None (0)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:47:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'None (0)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:47:11', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered 'No (N)'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-30T12:47:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '553a901f-4236-42a5-935b-725f38c6fafd' User entered '30 Oct 2020 12:47'	System	30 Oct 2020 16:47:17
	System	30 Oct 2020 16:47:17

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 5'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'None (0)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:41', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'None (0)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:45', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'None (0)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'None (0)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'None (0)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:52', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'None (0)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:55', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered 'No (N)'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-10-31T14:18:57', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c13e7a9c-7f67-42df-bf28-996ded67652f' User entered '31 Oct 2020 14:18'	System	31 Oct 2020 18:19:02
	System	31 Oct 2020 18:19:02

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 6'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:16', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'None (0)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'None (0)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:27', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'None (0)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'None (0)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:31', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'None (0)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:33', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'None (0)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered 'No (N)'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-01T13:25:38', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '77187e8c-44f9-4cb5-925f-b936082c81b3' User entered '01 Nov 2020 13:25'	System	01 Nov 2020 18:25:42
	System	01 Nov 2020 18:25:42

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	27 Oct 2020 18:52:44
User entered 'Day 7'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:48:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12'	System	02 Nov 2020 17:49:36
User entered 'No interference with activity (1)'	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:16', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered 'None (0)'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:18', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered 'None (0)'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:20', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered 'None (0)'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:22', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered 'None (0)'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:24', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered 'None (0)'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:28', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered 'No (N)'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-02T12:49:31', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ec0091c3-613c-42ea-b622-d2f022753b12' User entered '02 Nov 2020 12:49'	System	02 Nov 2020 17:49:36
	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 18:52:44

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	01 Nov 2020 18:25:10
User entered 'Day 8'	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:23', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '22e0c0f5-8660-48b5-af92-3e393333f409' User entered 'Yes (Y)'	System	03 Nov 2020 22:23:37
	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:31', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '22e0c0f5-8660-48b5-af92-3e393333f409' User entered '25'	System	03 Nov 2020 22:23:37
	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:35', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '22e0c0f5-8660-48b5-af92-3e393333f409' User entered '03 Nov 2020 17:23'	System	03 Nov 2020 22:23:37
	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	02 Nov 2020 17:48:50
User entered 'Day 9'	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-04T18:07:25', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '20739957-e589-423d-8d2f-ac15958806c4' User entered 'Yes (Y)'	System	04 Nov 2020 23:07:35
	System	04 Nov 2020 23:07:35

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-04T18:07:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '20739957-e589-423d-8d2f-ac15958806c4' User entered '25'	System	04 Nov 2020 23:07:35
	System	04 Nov 2020 23:07:35

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-04T18:07:32', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '20739957-e589-423d-8d2f-ac15958806c4' User entered '04 Nov 2020 18:07'	System	04 Nov 2020 23:07:35
	System	04 Nov 2020 23:07:35

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 17:48:50

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	03 Nov 2020 22:23:37
User entered 'Day 10'	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 15:20:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-05T14:04:05', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0dfa6a21-f4d2-46bc-abf5-463ab22bb049'	System	05 Nov 2020 19:04:13
User entered 'No (N)'	System	05 Nov 2020 19:04:13

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-05T14:04:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0dfa6a21-f4d2-46bc-abf5-463ab22bb049' User entered '05 Nov 2020 14:04'	System	05 Nov 2020 19:04:13
	System	05 Nov 2020 19:04:13

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	02 Nov 2020 17:49:36
User entered 'Day 8'	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:39', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9bda679f-27b2-4248-994b-673607739b47' User entered 'None (0)'	System	03 Nov 2020 22:23:45
	System	03 Nov 2020 22:23:45

US3152413

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:42', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9bda679f-27b2-4248-994b-673607739b47' User entered '03 Nov 2020 17:23'	System	03 Nov 2020 22:23:45
	System	03 Nov 2020 22:23:45

US3152413

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 17:49:36

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	01 Nov 2020 18:25:10
User entered 'Day 8'	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:47', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '55b5fd70-fe5a-46f1-bb25-8d260e84974d' User entered 'No (N)'	System	03 Nov 2020 22:23:54
	System	03 Nov 2020 22:23:54

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-03T17:23:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '55b5fd70-fe5a-46f1-bb25-8d260e84974d' User entered '03 Nov 2020 17:23'	System	03 Nov 2020 22:23:54
	System	03 Nov 2020 22:23:54

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '03 Nov 2020 12:00'	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '04 Nov 2020 11:59'	System	01 Nov 2020 18:25:10

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
Data entry locked.	System	03 Nov 2020 22:23:37
User entered 'Day 10'	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-05T14:04:12', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '915d763d-7e45-4071-8985-1c936a8578c0' User entered 'No (N)'	System	05 Nov 2020 19:04:17
	System	05 Nov 2020 19:04:17

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:20:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-05T14:04:14', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '915d763d-7e45-4071-8985-1c936a8578c0' User entered '05 Nov 2020 14:04'	System	05 Nov 2020 19:04:17
	System	05 Nov 2020 19:04:17

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:20:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 22:23:37

US3152413

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:20:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:55:14
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 22:23:37

US3152413

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	10 Nov 2020 17:04:24

US3152413

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '3 Nov 2020'	Devan Myers (b) (4)	10 Nov 2020 17:04:24

US3152413

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	10 Nov 2020 17:04:24

US3152413

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	10 Nov 2020 17:04:24

US3152413

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	10 Nov 2020 17:04:29

US3152413

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	10 Nov 2020 17:04:29

US3152413

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	10 Nov 2020 18:04:28

US3152413

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '10 Nov 2020'	Devan Myers (b) (4)	10 Nov 2020 18:04:28

US3152413

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	10 Nov 2020 18:04:28

US3152413

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Devan Myers (b) (4)	10 Nov 2020 18:04:28

US3152413

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Devan Myers (b) (4)	10 Nov 2020 18:04:33

US3152413

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	10 Nov 2020 18:04:33

US3152413

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:26

US3152413

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '17 Nov 2020'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:26

US3152413

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:26

US3152413

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:26

US3152413

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:36

US3152413

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	21 Dec 2020 19:58:36

US3152413

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:56

US3152413

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '24 Nov 2020'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:56

US3152413

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[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 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Clinic (Clinic)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:58:56

US3152413

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'VISIT3'	System	21 Dec 2020 19:58:56

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '24 Nov 2020'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '13:15'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered '24 Nov 2020 13:15'	System	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '36.7' C	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Oral (Oral)'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '72'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'bpm'	System	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '16'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'breaths/min'	System	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '102'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'mmHg'	System	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '78'	Priscilla Buahin (b) (4)	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'mmHg'	System	21 Dec 2020 19:59:50

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37

US3152413

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:20:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37

US3152413

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'No (N)'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:01

US3152413

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:20:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered empty.	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:01

US3152413

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:23

US3152413

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '24 Nov 2020'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:23

US3152413

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered '13:36'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:23

US3152413

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered '24 Nov 2020 13:36'	System	21 Dec 2020 20:00:23

US3152413

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 04:10:33
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:33

US3152413

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:37
User entered 'I'	System	21 Dec 2020 20:00:33

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-27T19:58:43', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4bcc856b-abea-4600-ad36-36a27a54de1d' User entered 'No (N)'	System	28 Nov 2020 00:58:52
	System	28 Nov 2020 00:58:52

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-27T19:58:46', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4bcc856b-abea-4600-ad36-36a27a54de1d' User entered 'No (N)'	System	28 Nov 2020 00:58:52

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-11-27T19:58:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4bcc856b-abea-4600-ad36-36a27a54de1d' User entered '27 Nov 2020 19:58:49'	System	28 Nov 2020 00:58:52
	System	28 Nov 2020 00:58:52

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-03T18:06:48', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '41d64cfc-f2b4-460e-8030-e419d6fb5e4e' User entered 'No (N)'	System	03 Dec 2020 23:07:17
	System	03 Dec 2020 23:07:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-03T18:07:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '41d64cfc-f2b4-460e-8030-e419d6fb5e4e'	System	03 Dec 2020 23:07:17
User entered 'No (N)'	System	03 Dec 2020 23:07:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-03T18:07:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '41d64cfc-f2b4-460e-8030-e419d6fb5e4e' User entered '03 Dec 2020 18:07:07'	System	03 Dec 2020 23:07:17
	System	03 Dec 2020 23:07:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-10T21:00:57', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4c58ab4f-c5ff-4391-9dab-fd1c63b22776'	System	11 Dec 2020 02:01:13
User entered 'No (N)'	System	11 Dec 2020 02:01:13

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-10T21:01:02', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4c58ab4f-c5ff-4391-9dab-fd1c63b22776'	System	11 Dec 2020 02:01:13
User entered 'No (N)'	System	11 Dec 2020 02:01:13

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-10T21:01:05', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '4c58ab4f-c5ff-4391-9dab-fd1c63b22776'	System	11 Dec 2020 02:01:13
User entered '10 Dec 2020 21:01:05'	System	11 Dec 2020 02:01:13

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-17T16:40:01', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '5e2c4835-be89-4045-ab70-a239d1e894a1' User entered 'No (N)'	System	17 Dec 2020 21:40:16
	System	17 Dec 2020 21:40:16

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-17T16:39:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '5e2c4835-be89-4045-ab70-a239d1e894a1' User entered 'No (N)'	System	17 Dec 2020 21:40:16
	System	17 Dec 2020 21:40:16

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-17T16:40:13', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '5e2c4835-be89-4045-ab70-a239d1e894a1' User entered '17 Dec 2020 16:40:13'	System	17 Dec 2020 21:40:16
	System	17 Dec 2020 21:40:16

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-25T19:45:22', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '546731d2-1863-48a0-87ca-33b7e8744aaf' User entered 'No (N)'	System	26 Dec 2020 03:45:42
	System	26 Dec 2020 03:45:42

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-25T19:45:26', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '546731d2-1863-48a0-87ca-33b7e8744aaf' User entered 'No (N)'	System	26 Dec 2020 03:45:42
	System	26 Dec 2020 03:45:42

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-25T19:45:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '546731d2-1863-48a0-87ca-33b7e8744aaf' User entered '25 Dec 2020 19:45:29'	System	26 Dec 2020 03:45:42
	System	26 Dec 2020 03:45:42

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-31T19:13:50', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8cccc6de-e6f5-450d-8f1a-5000e50a43d3'	System	01 Jan 2021 00:14:01
User entered 'No (N)'	System	01 Jan 2021 00:14:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-31T19:13:55', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8cccc6de-e6f5-450d-8f1a-5000e50a43d3'	System	01 Jan 2021 00:14:01
User entered 'No (N)'	System	01 Jan 2021 00:14:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2020-12-31T19:13:58', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '8cccc6de-e6f5-450d-8f1a-5000e50a43d3' User entered '31 Dec 2020 19:13:58'	System	01 Jan 2021 00:14:01
	System	01 Jan 2021 00:14:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-07T19:13:59', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'fbcc0403-97c0-4efa-bea1-f84b375b0af6' User entered 'No (N)'	System	08 Jan 2021 00:14:15
	System	08 Jan 2021 00:14:15

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-07T19:14:03', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'fbcc0403-97c0-4efa-bea1-f84b375b0af6' User entered 'No (N)'	System	08 Jan 2021 00:14:15
	System	08 Jan 2021 00:14:15

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-07T19:14:07', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'fbcc0403-97c0-4efa-bea1-f84b375b0af6' User entered '07 Jan 2021 19:14:07'	System	08 Jan 2021 00:14:15
	System	08 Jan 2021 00:14:15

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-14T13:05:42', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'f1fa6063-ee6f-4a43-9514-6c2710970758'	System	14 Jan 2021 18:06:17
User entered 'No (N)'	System	14 Jan 2021 18:06:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-14T13:05:49', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'f1fa6063-ee6f-4a43-9514-6c2710970758'	System	14 Jan 2021 18:06:17
User entered 'Yes (Y)'	System	14 Jan 2021 18:06:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Please 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-14T13:05:53', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'f1fa6063-ee6f-4a43-9514-6c2710970758'	System	14 Jan 2021 18:06:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 18:06:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-14T13:05:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'f1fa6063-ee6f-4a43-9514-6c2710970758' User entered '14 Jan 2021 13:05:56'	System	14 Jan 2021 18:06:17
	System	14 Jan 2021 18:06:17

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-21T16:49:05', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '385e0a59-8ebb-44d7-8881-126c87614b3e' User entered 'No (N)'	System	21 Jan 2021 21:49:14

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-21T16:49:08', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '385e0a59-8ebb-44d7-8881-126c87614b3e' User entered 'No (N)'	System	21 Jan 2021 21:49:14

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-21T16:49:11', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '385e0a59-8ebb-44d7-8881-126c87614b3e' User entered '21 Jan 2021 16:49:11'	System	21 Jan 2021 21:49:14
	System	21 Jan 2021 21:49:14

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-28T13:36:06', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '693d83d8-5c17-4dbe-a18c-558df5759e15'	System	28 Jan 2021 21:36:21
User entered 'No (N)'	System	28 Jan 2021 21:36:21

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-28T13:36:12', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '693d83d8-5c17-4dbe-a18c-558df5759e15'	System	28 Jan 2021 21:36:21
User entered 'No (N)'	System	28 Jan 2021 21:36:21

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-01-28T13:36:15', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '693d83d8-5c17-4dbe-a18c-558df5759e15' User entered '28 Jan 2021 13:36:15'	System	28 Jan 2021 21:36:21
	System	28 Jan 2021 21:36:21

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-04T18:26:56', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0c312ff8-95c2-4f34-b578-c39da37642e2'	System	04 Feb 2021 23:27:06
User entered 'No (N)'	System	04 Feb 2021 23:27:06

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-04T18:26:58', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0c312ff8-95c2-4f34-b578-c39da37642e2'	System	04 Feb 2021 23:27:06
User entered 'No (N)'	System	04 Feb 2021 23:27:06

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-04T18:27:01', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '0c312ff8-95c2-4f34-b578-c39da37642e2' User entered '04 Feb 2021 18:27:01'	System	04 Feb 2021 23:27:06
	System	04 Feb 2021 23:27:06

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-12T10:11:58', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd942fada-f2ab-4b73-a310-1860fbd0ef12' User entered 'No (N)'	System	12 Feb 2021 15:12:08
	System	12 Feb 2021 15:12:08

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-12T10:12:01', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd942fada-f2ab-4b73-a310-1860fbd0ef12'	System	12 Feb 2021 15:12:08
User entered 'No (N)'	System	12 Feb 2021 15:12:08

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-12T10:12:04', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'd942fada-f2ab-4b73-a310-1860fbd0ef12'	System	12 Feb 2021 15:12:08
User entered '12 Feb 2021 10:12:04'	System	12 Feb 2021 15:12:08

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-18T09:19:21', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'eefe196c-44cc-47a8-b5b0-15caf4c14ae7' User entered 'No (N)'	System	18 Feb 2021 14:19:35
	System	18 Feb 2021 14:19:35

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-18T09:19:26', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'eefe196c-44cc-47a8-b5b0-15caf4c14ae7' User entered 'No (N)'	System	18 Feb 2021 14:19:35
	System	18 Feb 2021 14:19:35

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-18T09:19:29', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'eefe196c-44cc-47a8-b5b0-15caf4c14ae7' User entered '18 Feb 2021 09:19:29'	System	18 Feb 2021 14:19:35
	System	18 Feb 2021 14:19:35

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-25T18:40:05-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1511036d-fe48-4ba2-9f6c-186f7aeb7672'	System	26 Feb 2021 07:01:44
User entered 'No (N)'	System	26 Feb 2021 07:01:44

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-25T18:40:09-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1511036d-fe48-4ba2-9f6c-186f7aeb7672'	System	26 Feb 2021 07:01:44
User entered 'No (N)'	System	26 Feb 2021 07:01:44

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-02-25T18:40:11-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '1511036d-fe48-4ba2-9f6c-186f7aeb7672'	System	26 Feb 2021 07:01:44
User entered '25 Feb 2021 23:40:11'	System	26 Feb 2021 07:01:44

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-06T11:57:20-08:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2c853efe-dee1-47b8-b393-926243e30d60'	System	06 Mar 2021 19:57:29
User entered 'No (N)'	System	06 Mar 2021 19:57:29

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-06T11:57:23-08:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2c853efe-dee1-47b8-b393-926243e30d60'	System	06 Mar 2021 19:57:29
User entered 'No (N)'	System	06 Mar 2021 19:57:29

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-06T11:57:25-08:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '2c853efe-dee1-47b8-b393-926243e30d60' User entered '06 Mar 2021 11:57:25'	System	06 Mar 2021 19:57:29
	System	06 Mar 2021 19:57:29

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-11T20:34:15-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '370e4f08-65f7-46d2-86a4-936ec06bef9d'	System	12 Mar 2021 01:34:28
User entered 'No (N)'	System	12 Mar 2021 01:34:28

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-11T20:34:19-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '370e4f08-65f7-46d2-86a4-936ec06bef9d'	System	12 Mar 2021 01:34:28
User entered 'No (N)'	System	12 Mar 2021 01:34:28

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-11T20:34:22-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '370e4f08-65f7-46d2-86a4-936ec06bef9d' User entered '11 Mar 2021 20:34:22'	System	12 Mar 2021 01:34:28
	System	12 Mar 2021 01:34:28

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-19T20:27:37-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a3ed2b4e-5517-4460-966f-a613eb992395'	System	20 Mar 2021 01:28:53
User entered 'No (N)'	System	20 Mar 2021 01:28:53

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-19T20:27:40-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a3ed2b4e-5517-4460-966f-a613eb992395'	System	20 Mar 2021 01:28:53
User entered 'No (N)'	System	20 Mar 2021 01:28:53

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-19T20:27:43-05:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'a3ed2b4e-5517-4460-966f-a613eb992395'	System	20 Mar 2021 01:28:53
User entered '19 Mar 2021 20:27:43'	System	20 Mar 2021 01:28:53

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-25T19:17:58-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '941f4a54-6d4a-441a-bef0-7959f642dc49'	System	26 Mar 2021 02:18:20
User entered 'No (N)'	System	26 Mar 2021 02:18:20

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-25T19:18:04-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '941f4a54-6d4a-441a-bef0-7959f642dc49'	System	26 Mar 2021 02:18:20
User entered 'No (N)'	System	26 Mar 2021 02:18:20

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-25T19:18:15-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '941f4a54-6d4a-441a-bef0-7959f642dc49'	System	26 Mar 2021 02:18:20
User entered '25 Mar 2021 19:18:15'	System	26 Mar 2021 02:18:20

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-01T18:10:36-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c169ef47-7be0-465c-b254-559b7427cffb'	System	02 Apr 2021 01:15:05
User entered 'No (N)'	System	02 Apr 2021 01:15:05

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-01T18:10:39-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c169ef47-7be0-465c-b254-559b7427cffb'	System	02 Apr 2021 01:15:05
User entered 'No (N)'	System	02 Apr 2021 01:15:05

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-01T18:10:41-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'c169ef47-7be0-465c-b254-559b7427cffb'	System	02 Apr 2021 01:15:05
User entered '01 Apr 2021 18:10:41'	System	02 Apr 2021 01:15:05

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-08T10:21:06-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3f2144d6-8d28-4be5-ab98-b0fba9f7c1cc'	System	08 Apr 2021 17:21:47
User entered 'Yes (Y)'	System	08 Apr 2021 17:21:47

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-08T10:21:10-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3f2144d6-8d28-4be5-ab98-b0fba9f7c1cc'	System	08 Apr 2021 17:21:47
User entered 'No (N)'	System	08 Apr 2021 17:21:47

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-08T10:21:13-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3f2144d6-8d28-4be5-ab98-b0fba9f7c1cc'	System	08 Apr 2021 17:21:47
User entered 'No (N)'	System	08 Apr 2021 17:21:47

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-08T10:21:17-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3f2144d6-8d28-4be5-ab98-b0fba9f7c1cc'	System	08 Apr 2021 17:21:47
User entered 'Yes (Y)'	System	08 Apr 2021 17:21:47

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Please 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-08T10:21:25-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3f2144d6-8d28-4be5-ab98-b0fba9f7c1cc'	System	08 Apr 2021 17:21:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 17:21:47

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-08T10:21:29-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '3f2144d6-8d28-4be5-ab98-b0fba9f7c1cc'	System	08 Apr 2021 17:21:47
User entered '08 Apr 2021 10:21:29'	System	08 Apr 2021 17:21:47

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-15T17:53:19-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9ff3f3dd-3cb7-4ca6-9fbe-c64b88aa9982' User entered 'No (N)'	System	16 Apr 2021 00:53:28

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-15T17:53:21-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9ff3f3dd-3cb7-4ca6-9fbe-c64b88aa9982'	System	16 Apr 2021 00:53:28
User entered 'No (N)'	System	16 Apr 2021 00:53:28

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-15T17:53:24-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '9ff3f3dd-3cb7-4ca6-9fbe-c64b88aa9982'	System	16 Apr 2021 00:53:28
User entered '15 Apr 2021 17:53:24'	System	16 Apr 2021 00:53:28

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-22T03:16:25-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '105a998f-759b-4b9d-be37-f4827c847e55'	System	22 Apr 2021 10:16:33
User entered 'No (N)'	System	22 Apr 2021 10:16:33

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-22T03:16:27-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '105a998f-759b-4b9d-be37-f4827c847e55'	System	22 Apr 2021 10:16:33
User entered 'No (N)'	System	22 Apr 2021 10:16:33

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-22T03:16:31-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '105a998f-759b-4b9d-be37-f4827c847e55'	System	22 Apr 2021 10:16:33
User entered '22 Apr 2021 03:16:31'	System	22 Apr 2021 10:16:33

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-29T00:02:27-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '673cda5a-3cd7-4dee-8862-24b7592fc998'	System	29 Apr 2021 07:02:39
User entered 'No (N)'	System	29 Apr 2021 07:02:39

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

Have you been exposed to someone with 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 (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-29T00:02:30-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '673cda5a-3cd7-4dee-8862-24b7592fc998'	System	29 Apr 2021 07:02:39
User entered 'No (N)'	System	29 Apr 2021 07:02:39

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-04-29T00:02:33-07:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: '673cda5a-3cd7-4dee-8862-24b7592fc998'	System	29 Apr 2021 07:02:39
User entered '29 Apr 2021 00:02:33'	System	29 Apr 2021 07:02:39

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 11:08:01

US3152413

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:20:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:08:01
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 11:08:01

US3152413

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:20:38

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 16:53:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-06T11:57:33-08:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ecd4f799-e248-4154-b7e1-2f55c846f154'	System	06 Mar 2021 19:58:04
User entered 'Yes (Y)'	System	06 Mar 2021 19:58:04

US3152413

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:20:38

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:53:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-06T11:57:52-08:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ecd4f799-e248-4154-b7e1-2f55c846f154'	System	06 Mar 2021 19:58:04
User entered 'Yes (Y)'	System	06 Mar 2021 19:58:04

US3152413

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:20:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:53:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3DD5D22-C475-4921-A477-41A54E630D45)', Time: '2021-03-06T11:57:55-08:00', User OID: 'PatientReportedOutcome (US3152413)', ODM File OID: 'ecd4f799-e248-4154-b7e1-2f55c846f154'	System	06 Mar 2021 19:58:04
User entered '06 Mar 2021 11:57:55'	System	06 Mar 2021 19:58:04

US3152413

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:46

US3152413

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered '21 Dec 2020'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:46

US3152413

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:46

US3152413

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered empty.	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:46

US3152413

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:08:16
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	21 Dec 2020 20:00:58

US3152413

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:31:34
User entered 'I'	System	21 Dec 2020 20:00:58

US3152413

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	Devan Myers (b) (4)	22 Jan 2021 18:07:34

US3152413

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '22 Jan 2021'	Devan Myers (b) (4)	22 Jan 2021 18:07:34

US3152413

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	22 Jan 2021 18:07:34

US3152413

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered empty.	Devan Myers (b) (4)	22 Jan 2021 18:07:34

US3152413

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	Devan Myers (b) (4)	22 Jan 2021 18:07:39

US3152413

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User entered 'I'	System	22 Jan 2021 18:07:39

US3152413

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:15:04

US3152413

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '22 Feb 2021'	Juliana DeVito (b) (4)	23 Feb 2021 18:15:04

US3152413

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Contact Made (CONTACT MADE)'	Juliana DeVito (b) (4)	23 Feb 2021 18:15:04

US3152413

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:15:04

US3152413

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:15:10

US3152413

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User entered 'I'	System	23 Feb 2021 18:15:10

US3152413

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:50:19

US3152413

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '23 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 13:50:19

US3152413

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Mar 2021 13:50:19

US3152413

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:20:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:50:19

US3152413

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:50:24

US3152413

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:20:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:15:25
User entered 'I'	System	23 Mar 2021 13:50:24

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '14 Jan 2021'	Oyebisi Olanrewaju (b) (4)	14 Jan 2021 19:20:54

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '13:06'	Oyebisi Olanrewaju (b) (4)	14 Jan 2021 19:20:54

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:47
User entered '14 Jan 2021 13:06'	System	14 Jan 2021 19:20:54

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Safety Call (Safety Call)'	Oyebisi Olanrewaju (b) (4)	14 Jan 2021 19:20:54

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:20:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	14 Jan 2021 19:20:54

US3152413

Folder: Covid-19 Assessment 14 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:20:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:01:53
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:41:18

US3152413

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 19:40:06

US3152413

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '6 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 19:40:06

US3152413

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Jan 2021 19:40:06

US3152413

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

Form: Visit Date

Generated On: 09 Jun 2021 15:20:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 19:40:06

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '6 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:18:56

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:18:56

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '6 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:47:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 09:47:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User entered empty.	System	07 Jan 2021 19:40:50

US3152413

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

Form: Unblinding

Generated On: 09 Jun 2021 15:20:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User entered empty.	System	07 Jan 2021 19:40:50

US3152413

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 19:41:16

US3152413

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '6 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 19:41:16

US3152413

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '14:39'	(b) (4), (b) (6)	07 Jan 2021 19:41:16

US3152413

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User entered '6 Jan 2021 14:39'	System	07 Jan 2021 19:41:16

US3152413

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 19:41:31

US3152413

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '6 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 19:41:31

US3152413

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '14:33'	(b) (4), (b) (6)	07 Jan 2021 19:41:31

US3152413

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:19
User entered '6 Jan 2021 14:33'	System	07 Jan 2021 19:41:31

US3152413

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:20:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:58:19
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:04:04

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:06:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:06:43
Data point term sent to Coder	System	20 Oct 2020 21:06:02
User entered 'sinus infection'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User entered empty.	System	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	17 Nov 2020 18:45:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '25 Oct 2020' reason for change: New Information	Juliana DeVito (b) (4)	17 Nov 2020 18:45:20
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User entered empty.	System	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	17 Nov 2020 18:45:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User entered '0'	System	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58
User entered 'I'	System	20 Oct 2020 21:05:07

US3152413

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:58

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:42:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4)	21 Dec 2020 22:14:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Dec 2020 22:14:54
Data point term sent to Coder	System	21 Dec 2020 20:41:21
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Priscilla Buahin (b) (4)	21 Dec 2020 20:41:01
Coding entries removed.	Priscilla Buahin (b) (4)	21 Dec 2020 20:40:54
User entered 'INJECTION SITE REDNESS - Non-urticarial' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	21 Dec 2020 20:40:54
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:17:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:52:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 14:52:20
Data point term sent to Coder	System	05 Nov 2020 14:51:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Injection site redness'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Redness at injection Site on 28 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:43:18
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Redness at injection Site on 28 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Updated' (Site from DM).	Priscilla Buahin (b) (4)	21 Dec 2020 19:33:58
User entered '28 Oct 2020' reason for change: Per Query Resolution	(b) (4)	21 Dec 2020 19:33:46
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Redness at injection Site on 28 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:18:15
User entered '04 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 04:43:20
Query 'Data is required. Please provide.' answered with 'Data not reported' (Site from System).	Priscilla Buahin (b) (4)	21 Dec 2020 19:34:09
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Dec 2020 19:33:46
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User entered empty.	System	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)' reason for change: Data Entry Error	Devan Myers (b) (4)	10 Nov 2020 17:23:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '06 Nov 2020' reason for change: Data Entry Error	Devan Myers (b) (4)	10 Nov 2020 17:23:52
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 04:43:22
Query 'Data is required. Please provide.' answered with 'data was not reported' (Site from System).	Priscilla Buahin (b) (4)	21 Dec 2020 19:34:23
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Dec 2020 19:33:46
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User entered empty.	System	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Devan Myers (b) (4)	10 Nov 2020 17:23:52
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:51:01
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 14:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:50:46
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 14:51:01
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 14:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:50:46
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0' reason for change: Data Entry Error	Devan Myers (b) (4)	10 Nov 2020 17:23:52
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '1' reason for change: Data Entry Error	Devan Myers (b) (4)	10 Nov 2020 17:23:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Devan Myers (b) (4)	10 Nov 2020 17:23:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User entered '0'	System	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03
User entered '0'	System	05 Nov 2020 14:50:46

US3152413

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:03

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 15:36:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 15:36:17
Data point term sent to Coder	System	26 Jan 2021 15:35:09
User entered 'panic attacks'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '10 Nov 2020'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'None (NONE)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:06:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updating conmeds' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	23 Feb 2021 18:16:38
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 21:49:18
User entered 'I'	Azure Erskine (b) (4) (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[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 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 15:34:21

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal infection, LLT: Yeast infection - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 15:37:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 15:37:11
Data point term sent to Coder	System	26 Jan 2021 15:36:09
User entered 'yeast infection'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '09 Nov 2020'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User entered empty.	System	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '10 Nov 2020'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User entered empty.	System	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'None (NONE)'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'I'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 15:35:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 15:35:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Azure Erskine (b) (4)	26 Jan 2021 15:35:47
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 15:35:42
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User entered '0'	System	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24
User entered 'I'	System	26 Jan 2021 15:35:42

US3152413

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:25:24

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 05:51:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 05:51:52
Data point term sent to Coder	System	23 Feb 2021 18:18:40
User entered 'worsening of cervical disc compression with radiculopathy'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '3 Jan 2021'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Related (NOT RELATED)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'None (NONE)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '1'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[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 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:15:03
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 18:18:28

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:35:57
User entered 'USA-US073-2021-mRNA-1273-P301000012'	System	08 Apr 2021 22:35:15
User entered 'New'	(b) (4), (b) (6)	08 Apr 2021 22:35:15

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:02
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 18:17:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 18:17:52
Data point term sent to Coder	System	08 Apr 2021 18:16:30
User entered 'cholecystitis'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:04
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:05
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:08
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:09
User entered '06 Apr 2021'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:11
User entered empty.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:13
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:15
User entered '08 Apr 2021'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:16
User entered empty.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:20
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:22
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:23
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 17:41:43
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:26
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'unknown at this time subject not yet discharged as of 08 apr 2021 when site was notified of admission ' (Site from System).	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:17:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Apr 2021 18:16:05
User entered 'I'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:38
User entered '08 Apr 2021'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:05:50
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'Subject has refused to sign a medical release for site to obtain relevant medical records to complete this SAE. Subject has since withdrawn consent for study participation and is unwilling to provide site with any further update for this SAE. Site does not have this information.' (Site from Safety).	Priscilla Buahin (b) (4) (b) (4)	30 Apr 2021 14:16:22
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:48:16
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:39
User entered empty.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 17:41:32
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:45
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'unknown at this time subject not yet discharged as of 08 apr 2021 when site was notified of admission ' (Site from System). User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). User entered 'Unknown (UNK)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:17:42
	System	08 Apr 2021 18:16:05
	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:38:43
User entered empty.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:01
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:05
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:08
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:19
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:21
User entered 'Not Applicable (NOT APPLICABLE)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:23
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:25
User entered '0'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:27
User entered 'I'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:33
User entered empty.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Did subject receive any treatment aside from the cholecystectomy? Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:05:56
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)	03 May 2021 15:05:55
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:05:53
Query 'PV Query: Did subject receive any treatment aside from the cholecystectomy? Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Subject has refused to sign a medical release for site to obtain relevant medical records to complete this SAE. Subject has since withdrawn consent for study participation and is unwilling to provide site with any further update for this SAE. Site does not have this information.' (Site from Safety).	Priscilla Buahin (b) (4) (b) (4)	30 Apr 2021 14:17:13

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[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. ' answered with 'Subject has refused to sign a medical release for site to obtain relevant medical records to complete this SAE. Subject has since withdrawn consent for study participation and is unwilling to provide site with any further update for this SAE. Site does not have this information.' (Site from Safety).	Priscilla Buahin (b) (4)	30 Apr 2021 14:16:55
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Subject has refused to sign a medical release for site to obtain relevant medical records to complete this SAE. Subject has since withdrawn consent for study participation and is unwilling to provide site with any further update for this SAE. Site does not have this information.' (Site from Safety).	Priscilla Buahin (b) (4)	30 Apr 2021 14:16:41
User opened query 'PV Query: Did subject receive any treatment aside from the cholecystectomy? Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:48:48
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)	13 Apr 2021 20:48:24

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:48:02
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:34
User entered 'subject informed site of admission post cholecystectomy. Indication for cholecystectomy was cholecystitis. Medical records pending.'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 18:16:05

US3152413

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 18:16:05

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:58:19
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:12:06
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 20:02:28
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'botox captured on con med log' (Site from DM).	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:04:09
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:17:28
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:01:30

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	23 Feb 2021 18:54:04
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Jan 2021 10:22:55
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:29:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:46:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:46:46
Data point term sent to Coder	System	19 Oct 2020 19:35:03
Coding entries removed.	Devan Myers (b) (4)	19 Oct 2020 19:34:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 00:44:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 00:44:43
Data point term sent to Coder	System	29 Sep 2020 15:31:38
User entered 'Propranolol'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:27:41
Query 'Per MM: Please clarify indication.' answered with 'clarified' (Site from DM).	Devan Myers (b) (4)	19 Oct 2020 19:35:03
User entered 'MEDICAL HISTORY - migraines' reason for change: Data Entry Error	Devan Myers (b) (4)	19 Oct 2020 19:34:55
User opened query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:31:35
User entered 'Medical History'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '10'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'three times daily (TID)'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'UN UNK 2018'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:30:53

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: BLISOVI 24 FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:07:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 12:07:17
Data point term sent to Coder	System	26 Jan 2021 15:19:54
Coding entries removed.	Juliana DeVito (b) (4)	26 Jan 2021 15:18:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: BLISOVI 24 FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 14:40:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 14:40:57
Data point term sent to Coder	System	19 Oct 2020 19:36:04
Coding entries removed.	Devan Myers (b) (4)	19 Oct 2020 19:35:39

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: BLISOVI 24 FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 07:36:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 07:36:43
Data point term sent to Coder	System	29 Sep 2020 15:33:41
User entered 'Blisovi'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'polycystic OVARIAN SYNDROME' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:18:58
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4)	
Query 'Per MM: Please clarify indication.' answered with 'updated accordingly ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:38:13
User entered 'MEDICAL HISTORY - Polycystic Ovarian Syndrome' reason for change: Data Entry Error	Devan Myers (b) (4)	19 Oct 2020 19:36:01
User opened query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4)	
User entered 'Medical History'	Devan Myers (b) (4)	19 Oct 2020 19:35:39
	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 16:47:27
	(b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:15:53
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable. ' answered with 'updated per source' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:19:41
User entered '1/.02' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:18:58
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:43:23
User entered '110.02'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:18:58
User entered 'mg (mg)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg/mg' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:18:58
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'once daily (QD)'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

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

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'UN UNK 2010'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:32:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 15:32:55
User entered 'No (N)' reason for change: Data Entry Error	Devan Myers (b) (4)	29 Sep 2020 15:32:55
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:32:49
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:32:49

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:23:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:23:14
Data point term sent to Coder	System	26 Jan 2021 15:22:58
Coding entries removed.	Juliana DeVito (b) (4)	26 Jan 2021 15:22:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 19:39:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 19:39:28
Data point term sent to Coder	System	19 Oct 2020 19:37:07
Coding entries removed.	Devan Myers (b) (4)	19 Oct 2020 19:36:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 15:35:51

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Sep 2020 15:35:51
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	29 Sep 2020 15:34:43
User entered 'Allegra'	Devan Myers (b) (4)	29 Sep 2020 15:34:21
	(b) (4)	

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'sEASONAL ALLERGIES' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:22:18
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4)	
Query 'Per MM: Please clarify indication.' answered with 'updated accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:38:22
User entered 'MEDICAL HISTORY - seasonal allergies' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per MM: Please clarify indication.' (Site from DM).	Devan Myers (b) (4)	19 Oct 2020 19:36:50
User entered 'Medical History'	(b) (4)	
	Devan Myers (b) (4)	19 Oct 2020 19:36:35
	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:39:01
	(b) (4)	
	Devan Myers (b) (4)	29 Sep 2020 15:34:21
	(b) (4)	

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:16:06
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:22:26
User entered '1' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:22:18
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:44:05
User entered '5'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:22:18
User entered 'mg (mg)'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'once daily (QD)'	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'UN UNK 2000'	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:34:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 15:34:28
User entered 'No (N)' reason for change: Data Entry Error	Devan Myers (b) (4)	29 Sep 2020 15:34:28
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:34:21
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:34:21

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:04:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:04:00
Data point term sent to Coder Coding entries removed.	System Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:23:58 26 Jan 2021 15:23:24
User entered 'CLINDAMYCIN 1.0%' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:23:24
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:39:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:39:28
Data point term sent to Coder Coding entries removed.	System Devan Myers (b) (4) (b) (4)	19 Oct 2020 19:38:09 19 Oct 2020 19:37:13
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:52:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:52:38
Data point term sent to Coder	System	29 Sep 2020 15:35:47

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Clindamycin'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:38:28
Query 'Per MM: Please clarify indication.' answered with 'updated accordingly' (Site from DM).	Devan Myers (b) (4)	19 Oct 2020 19:37:21
User entered 'Acne' reason for change: Data Entry Error	Devan Myers (b) (4)	19 Oct 2020 19:37:13
User opened query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:18:52
User entered 'Medical History'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:16:20
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:23:30
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:44:47
User entered 'I'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Other (OTHER)'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'application' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:23:24
User entered 'Percent'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'once daily (QD)'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Topical (TOPICAL)'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'UN UNK 2018'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:35:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 15:35:49
User entered 'No (N)' reason for change: Data Entry Error	Devan Myers (b) (4)	29 Sep 2020 15:35:49
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:35:45
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:35:45

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: RETINOIDS FOR TOPICAL USE IN ACNE, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:39:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:39:28
Data point term sent to Coder Coding entries removed.	System Devan Myers (b) (4) (b) (4)	19 Oct 2020 19:38:10 19 Oct 2020 19:37:45
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: TRETINOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:15:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:15:40
Data point term sent to Coder User entered 'Tretinoin'	System Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:37:51 29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:38:34
Query 'Per MM: Please clarify indication.' answered with 'updated accordingly' (Site from DM).	Devan Myers (b) (4)	19 Oct 2020 19:38:47
User entered 'Acne' reason for change: Data Entry Error	Devan Myers (b) (4)	19 Oct 2020 19:37:45
User opened query 'Per MM: Please clarify indication.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:32:45
User entered 'Medical History'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:16:33
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'updated' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:24:26
User entered '1' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	26 Jan 2021 15:24:01
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 07:45:13
User entered '0.025'	Devan Myers (b) (4) (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:24:01
User entered 'g (g)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:23:50
User entered 'mg (mg)'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'application' reason for change: Data Entry Error	Juliana DeVito (b) (4)	26 Jan 2021 15:24:01
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'once daily (QD)'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Topical (TOPICAL)'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'UN UNK 2018'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 15:37:29

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 15:16:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 15:16:15
Data point term sent to Coder	System	26 Oct 2020 15:06:21
User entered 'Doxycycline'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Sinus Infection'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '100'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'three times daily (TID)'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '20 Oct 2020'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	27 Oct 2020 18:45:47
User entered '25 Oct 2020' reason for change: Data Entry Error	Devan Myers (b) (4)	27 Oct 2020 18:45:47
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	26 Oct 2020 15:06:06
User entered '27 Oct 2020'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User entered '3'	System	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User entered '1'	System	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:31
User entered '804 (804)'	System	26 Oct 2020 15:06:06

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 13:58:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 13:58:22
Data point term sent to Coder	System	04 Nov 2020 13:57:38
User entered 'Advil'	Devan Myers (b) (4) (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:41:42
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'Confirmed. Solicited adverse reaction of injection site pain did not meet the AE reporting criteria.' (Site from DM).	Priscilla Buahin (b) (4) (b) (4)	21 Dec 2020 19:42:01

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:41:04
User entered 'Injection site pain'	Devan Myers (b) (4) (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '400'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'as needed (PRN)'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '28 Oct 2020'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '28 Oct 2020'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User entered empty.	System	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User entered empty.	System	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:34
User entered empty.	System	04 Nov 2020 13:57:02

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:25:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:25:51
Data point term sent to Coder	System	10 Nov 2020 18:05:58
Coding entries removed.	Devan Myers (b) (4) (b) (4)	10 Nov 2020 18:04:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:24:38
Data point term sent to Coder	System	10 Nov 2020 17:23:49
User entered 'Advil'	Devan Myers (b) (4) (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, however, there is no record of this event in Diary (04Nov2020). Review if this should be updated to NO. Else, provide clarification ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 04:51:01
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, however, there is no record of this event in Diary (04Nov2020). Review if this should be updated to NO. Else, provide clarification ' answered with 'Subject reported taking this medication for documented indication to the site during the safety call. Not noted in the diary because this event was after the first 7 days and the diary did not ask about medications then. ' (Site from DM).	Priscilla Buahin (b) (4)	21 Dec 2020 19:56:53
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, however, there is no record of this event in Diary (04Nov2020). Review if this should be updated to NO. Else, provide clarification ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 02:41:22
User entered 'INJECTION SITE Redness' reason for change: Data Entry Error	Devan Myers (b) (4)	10 Nov 2020 18:04:58
User entered 'Injection site pain'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '200'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'as needed (PRN)'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '04 Nov 2020'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '06 Nov 2020'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Devan Myers (b) (4)	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User entered empty.	System	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User entered empty.	System	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:41
User entered empty.	System	10 Nov 2020 17:23:09

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:39:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:39:20
Data point term sent to Coder	System	26 Jan 2021 15:38:12
User entered 'fluconazole'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'yeast infection'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '150'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'once (ONCE)'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '10 Nov 2020'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '10 Nov 2020'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User entered empty.	System	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User entered empty.	System	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:44
User entered empty.	System	26 Jan 2021 15:37:16

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening ANXIETY during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:04:09
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:47:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 20:47:53
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening ANXIETY during this timeframe; update Con Med indication or provide clarification. ' answered with 'Confirmed with subject. Medication was prescribed for a new diagnosis which is the AE Panic Attacks not for Worsening Anxiety.' (Site from DM).	Priscilla Buahin (b) (4)	08 Apr 2021 20:20:47
Data point term sent to Coder	System	08 Apr 2021 20:19:32
Coding entries removed.	Priscilla Buahin (b) (4)	08 Apr 2021 20:18:58
User entered 'ATIVAN' reason for change: Per Query Resolution	Priscilla Buahin (b) (4)	08 Apr 2021 20:18:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:32:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:32:27
Data point term sent to Coder	System	24 Mar 2021 17:00:43

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ATIVAN (worsening anxiety)' reason for change: Per Query Resolution	Azure Erskine (b) (4)	24 Mar 2021 17:00:26
Coding entries removed.	(b) (4)	
	Azure Erskine (b) (4)	24 Mar 2021 16:59:50
	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening ANXIETY during this timeframe; update Con Med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:51:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 12:22:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 12:22:00
	(b) (4)	
Data point term sent to Coder	System	23 Feb 2021 18:42:10
Coding entries removed.	Juliana DeVito (b) (4)	23 Feb 2021 18:41:44
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:43:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:43:10
	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 15:42:20
User entered 'Ativan'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13
	(b) (4)	

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'PANIC ATTACKS' reason for change: Data Entry Error	Azure Erskine (b) (4)	24 Mar 2021 16:59:50
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4)	26 Feb 2021 10:12:52
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	Juliana DeVito (b) (4)	23 Feb 2021 18:41:51
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'ANXIETY, panic attacks' reason for change: Data Entry Error	Juliana DeVito (b) (4)	23 Feb 2021 18:41:44
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:55:55
User entered 'anxiety'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13
	(b) (4)	

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0.5'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'as needed (PRN)'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '10 Nov 2020'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Azure Erskine (b) (4)	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 15:42:13

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:46:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:46:15
Data point term sent to Coder	System	23 Feb 2021 18:44:13
User entered 'hydrocodone-acetaminophen'	Juliana DeVito (b) (4) (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'worsening of cervical disc compression with radiculopathy'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '5-325'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'mg (mg)'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'as needed (PRN)'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Oral (ORAL)'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '06 Jan 2021'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	Juliana DeVito (b) (4)	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:43:12

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 13:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 13:53:36
Data point term sent to Coder	System	23 Mar 2021 13:53:06
User entered 'Botox'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'migraines'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '70' reason for change: New Information	(b) (4), (b) (6)	07 Apr 2021 19:26:52
User entered 'UNK'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Other (OTHER)'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'units' reason for change: New Information	(b) (4), (b) (6)	07 Apr 2021 19:26:52
User entered 'UNK'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '28 Jan 2021'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered '28 Jan 2021'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User entered empty.	System	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User entered empty.	System	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:20:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:57:49
User entered empty.	System	23 Mar 2021 13:52:40

US3152413

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:20:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:58:19
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:59
User entered 'Yes (Y)' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:05:34
User entered 'No (N)'	Juliana DeVito (b) (4)	26 Jan 2021 15:27:03
	(b) (4)	

US3152413

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:20:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:46
User entered '08 Apr 2021'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:06:45

US3152413

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:20:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:48
User entered 'cholecystectomy'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:06:45

US3152413

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:20:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:50
User entered 'Adverse Event (AE)'	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:06:45

US3152413

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:20:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:25:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:40:10
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:39:51
User entered empty.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 18:06:45

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'USA-US073-2021-MRNA-1273-P301000012'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Yes (Y)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Yes (Y)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Brandon'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Essink'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered '3319 N 107th'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Omaha'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered '68134'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'US'	System	08 Apr 2021 22:36:18

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 22:36:18

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'USA-US073-2021-MRNA-1273-P301000012'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

Serious

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Yes (Y)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Yes (Y)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'No (N)'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Brandon'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Essink'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered '3319 N 107th'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered 'Omaha'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:36:12
User entered '68134'	System	08 Apr 2021 22:35:15

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered 'US'	System	08 Apr 2021 22:36:18

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:20:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 22:36:18

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:20:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:42:47
User entered '08/Apr/2021 18:36'	System	08 Apr 2021 22:36:18

US3152413

Folder: SAE USA-US073-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:20:38

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 17:42:47
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 22:36:18