

US3412030 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:28:51

All time stamps listed in this document are displayed in GMT

US3412030

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

[Participant ID](#)

US3412030

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

US3412030

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:22:38

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 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) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Date of Informed Consent (*dd MMM yyyy*) 30 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input 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) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:22:38

Generated On: 09 Jun 2021 17:28:51

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	BPH
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	RIGHT MINISCUS REPAIR
Start date (dd MMM yyyy)	UN UNK 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 UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	LEFT MINISCUS REPAIR
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	BACKPAIN / MUSCLE SPASMS (2DEGREES) TO SHOULDER REPAIR
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 04:22:37

Generated On: 09 Jun 2021 17:28:51

Condition	PLANTAR FASCIITIS
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)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:22:38

Generated On: 09 Jun 2021 17:28:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 09:00
Height (<i>xxx.x</i>)	195.5 cm
Weight (<i>xxx.x</i>)	98.3 kg
BMI (<i>xxx.x</i>)	25.71935 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:22:38

Generated On: 09 Jun 2021 17:28:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:22:38

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:22:38

Generated On: 09 Jun 2021 17:28:51

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 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) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

What was the date of randomization? (dd MMM yyyy) 30 JUL 2020

What was the participant's randomization number? 100237

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

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) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

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)	30 JUL 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 09:00
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

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)	30 JUL 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 10:17
Temperature (xxx.x)	95.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 30 JUL 2020 09:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 JUL 2020
Collection time (00:00-23:59)	09:29 (24 HR)
Collection date and time (derived)	30 JUL 2020 09:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Collection date (dd MMM yyyy)			30 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:32	30 JUL 2020 09:32
Nasopharyngeal Swab 2	No		

US3412030

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

95.6 °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 JUL 2020 10:23

PC Open Date & Time

30 JUL 2020 10:05

PC Close Date & Time

30 JUL 2020 12:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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 97.2 °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	30 JUL 2020 21:30
PC Open Date & Time	30 JUL 2020 13:30
PC Close Date & Time	31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

95.2 °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

01 AUG 2020 21:08

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 20:23

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

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

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

PC Time Stamp 03 AUG 2020 20:18

PC Open Date & Time 03 AUG 2020 12:00

PC Close Date & Time 04 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 22:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

98.2 °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

05 AUG 2020 20:15

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 10:24

PC Open Date & Time

30 JUL 2020 10:05

PC Close Date & Time

30 JUL 2020 12:35

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

30 JUL 2020 21:31

PC Open Date & Time

30 JUL 2020 13:30

PC Close Date & Time

31 JUL 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 21:08

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 20:23

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 20:18

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

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 AUG 2020 22:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

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 AUG 2020 20:16

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 10:25
PC Open Date & Time	30 JUL 2020 10:05
PC Close Date & Time	30 JUL 2020 12:35

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 21:32
PC Open Date & Time	30 JUL 2020 13:30
PC Close Date & Time	31 JUL 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

Yes ☐

PC Time stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:09
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

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 ☒

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 20:23
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

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 ☒

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EAB) (1725)

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US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 20:19
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

58 of 2296

EAB) (1725)

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 22:02
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

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 ☒

PRODUCTION RELEASE (v12.003

60 of 2296

EAB) (1725)

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 20:16
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

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 AUG 2020
Time of assessment (00:00-23:59)	07:42 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 07:42
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	09:02 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:02
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3412030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

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 AUG 2020

What was the treatment time? (00:00-23:59) 08:25 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 08:25

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

US3412030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	08:13 (24 HR)
Collection date and time (derived)	27 AUG 2020 08:13

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:17	27 AUG 2020 08:17
Nasopharyngeal Swab 2	No		

US3412030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 AUG 2020 09:04

PC Open Date & Time

27 AUG 2020 08:45

PC Close Date & Time

27 AUG 2020 11:15

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

97.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp	27 AUG 2020 21:49
PC Open Date & Time	27 AUG 2020 12:10
PC Close Date & Time	28 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

97.2 °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

28 AUG 2020 20:02

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

95.6 °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 AUG 2020 15:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 20:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

01 SEP 2020 07:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 08:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 09:05

PC Open Date & Time

27 AUG 2020 08:45

PC Close Date & Time

27 AUG 2020 11:15

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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 AUG 2020 21:49

PC Open Date & Time

27 AUG 2020 12:10

PC Close Date & Time

28 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:02

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 15:15

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 07:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

02 SEP 2020 08:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

02 SEP 2020 19:51

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 09:05
PC Open Date & Time	27 AUG 2020 08:45
PC Close Date & Time	27 AUG 2020 11:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 21:50
PC Open Date & Time	27 AUG 2020 12:10
PC Close Date & Time	28 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

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 ☒

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:03
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

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
EAB) (1725)

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US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 15:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

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 ☒

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

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)

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 07:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

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 ☒

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 08:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

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 ☒

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:51
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:28:51

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

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 9

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

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:22:28

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:42:18

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	VISIT3

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:42:18

Generated On: 09 Jun 2021 17:28:51

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:42:18

Generated On: 09 Jun 2021 17:28:51

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.

US3412030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:42:18

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	09:22 (24 HR)
Collection date and time (derived)	25 SEP 2020 09:22

US3412030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:42:05

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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°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="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"/>

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

Patient Cloud Open Date & Time

29 SEP 2020 00:01

Patient Cloud Close Date & Time

03 OCT 2020 23:59

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 09:50:09

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 13:52:31

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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°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="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"/>

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 106
Have 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°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="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"/>

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 113
Have 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°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="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"/>

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 117

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 17:58:39

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☒

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

05 DEC 2020 08:25:08

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 DEC 2020 07:29:49

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 13:05:54

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

26 DEC 2020 06:40:23

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

02 JAN 2021 06:22:26

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	09 JAN 2021 07:44:33
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

16 JAN 2021 09:21:36

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

23 JAN 2021 10:27:22

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 10:25:56
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 19:09:20
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

20 FEB 2021 20:55:24

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

28 FEB 2021 21:36:53

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☒

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 15:09:36

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 12:44:12
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☒

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 MAR 2021 10:18:19

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 08:27:10

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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="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°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="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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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="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	27 APR 2021 18:07:50
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 12:59:53

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 334

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

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

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

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

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

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

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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°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="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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 439

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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="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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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="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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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="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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 628

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

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

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

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

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

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

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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°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="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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 733

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

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

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

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

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

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

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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"/>

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 754

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3412030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:28:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		22 MAR 2021 10:18:36

US3412030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:50

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:50

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT NOT CONTACTED DUE
TO SITE ERROR. SITE STAFF
INSTRUCTED TO COMPLETE
SAFETY CALLS ALONGSIDE
OPEN LABEL PHASE

US3412030

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	07:52 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 07:52
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

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.

US3412030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	08:00 (24 HR)
Collection date and time (derived)	04 MAR 2021 08:00

US3412030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:44

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412030

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:28:51

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412030

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

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

Visit date (dd MMM yyyy)	5 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3412030

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:38:34

Generated On: 09 Jun 2021 17:28:51

Date of updated informed consent (<i>dd MMM yyyy</i>)	5 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 DEC 2020
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3412030

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Height	185.2 cm
Weight	99.8 kg
BMI (xxx.x)	29.09702

US3412030

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Height	185.2 cm
Weight	99.8 kg
BMI (xxx.x)	29.09702
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)	5 JAN 2021
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 14:05
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3412030

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Height	185.2 cm
Weight	99.8 kg
BMI (xxx.x)	29.09702
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 JAN 2021
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 14:53
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412030

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3412030

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 5 JAN 2021

What was the treatment time? (00:00-23:59) 14:21 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 14:21

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

US3412030

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00-23:59)	14:11 (24 HR)
Collection date and time (derived)	5 JAN 2021 14:11

US3412030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	14:12
Collection Date and Time (derived)	5 JAN 2021 14:12

US3412030

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:50

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:50

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	OLD29

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 10:05
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 11:28
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412030

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3412030

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 2 FEB 2021

What was the treatment time? (00:00-23:59) 10:57 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 10:57

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

US3412030

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:50

Generated On: 09 Jun 2021 17:28:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:50

Generated On: 09 Jun 2021 17:28:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412030

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	07:52 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 07:52
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 15:08:43

Generated On: 09 Jun 2021 17:28:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	08:00 (24 HR)
Collection date and time (derived)	04 MAR 2021 08:00

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:25:46

Generated On: 09 Jun 2021 17:28:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

AEID

Adverse event

MULTIPLE BEE STINGS
GENERALIZED PRIMARILY ON
LOWER EXTREMITIES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 AUG 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 (1)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

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 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)	

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

AEID

Adverse event

BRIEF INTERMITTENT
DIZZINESS

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)

07 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 AUG 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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EAB) (1725)

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US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3412030

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

AEID

Adverse event

WORSENING BACK
PAIN/MUSCLE SPASM

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)

14 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 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 (3)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

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 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)	

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

AEID	USA-US061-2021-MRNA-1273-P30 1000019
Adverse event	WORSENING BPH/URINARY RETENTION
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)	18 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)	22 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 type="radio"/> Grade 4 <input checked="" 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)	18 APR 2021
Hospital Discharge Date (dd MMM yyyy)	22 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

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 <input type="radio"/>
	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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

SITE WAS NOTIFIED OF SAE
DURING SAFETY CALL
COMPLETED ON 27 APR 2021.
PATIENT PRESENTED TO THE
ED ON 18 APR 2021 FOR
URINARY RETENTION. PATIENT
WAS HOSPITALIZED UNTIL 22
APR 2021 FOLLOWING
PATIENT'S TURP PROCEDURE.
SAE HAS RESOLVED.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

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

Yes ☒

No ☐

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

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	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 1990
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 (2)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<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) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration .4

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 (4)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	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 2017	
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 (5)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MULTIPLE BEE STINGS
GENERALIZED BUT PRIMAIRLY
ON LEGS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	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)	03 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 AUG 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 (6)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASM / BACK PAIN

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	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)	14 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN / MUSCLE SPASM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	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 1990
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication PLANTAR FASCIITIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	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 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)	30 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"/>

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

Name of Medication VOLTAREN

Prophylaxis Yes ☐
No ☒

Indication PLANTAR FASCIITIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 15:08:42

Generated On: 09 Jun 2021 17:28:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 DEC 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"/>

US3412030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

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) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

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

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:28:51

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

US3412030

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:28:51

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 ☐

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

SAEID	USA-US061-2021-MRNA-1273-P301000019
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:46:18

Generated On: 09 Jun 2021 17:28:51

SAEID	USA-US061-2021-MRNA-1273-P301000019
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	27/APR/2021 12:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412030 (Prod: New Horizons Clinical Research)

US3412030

Form: Participant Creation

Generated On: 09 Jun 2021 17:28:51

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'US3412030'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 12:44:25

US3412030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:45:25

US3412030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 12:44:26

US3412030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:45:25

US3412030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'SCRN'	System	30 Jul 2020 13:45:25

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 12:44:27

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '61'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'YEARS'	System	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '61'	System	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:01

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jul 2020'	System	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2020'	System	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:43

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Jul 2020 13:47:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jul 2020 13:46:43

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	(b) (4)	30 Jul 2020 13:47:11
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	30 Jul 2020 13:46:43
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 12:44:26

US3412030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'I'	System	30 Jul 2020 13:47:21

US3412030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:47:21

US3412030

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:28:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:07:15

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:09:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:09:00
Data point term sent to Coder	System	05 Aug 2020 18:07:57
User entered 'Hypertension'	(b) (4), (b) (6)	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'UN UNK 1988'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 1988'	System	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '1988'	System	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Aug 2020 18:07:48

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:10:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:10:03
Data point term sent to Coder	System	05 Aug 2020 18:08:57
User entered 'GERD'	(b) (4), (b) (6)	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2019'	System	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2019'	System	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Aug 2020 18:08:08

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:18:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:18:04
Data point term sent to Coder	System	05 Aug 2020 18:17:21
User entered 'BPH'	(b) (4), (b) (6)	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2017'	System	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2017'	System	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Aug 2020 18:16:36

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 18:47:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 18:47:19
Data point term sent to Coder	System	05 Oct 2020 18:46:01
User entered 'vasectomy'	Jacob sekinger (b) (4)	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 1989'	Jacob sekinger (b) (4)	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 1989'	Jacob sekinger (b) (4)	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 1989'	System	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '1989'	System	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 1989'	System	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '1989'	System	05 Oct 2020 18:44:49

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:06:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'no known underlying condition which led to this procedure, most likely caused by age. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	28 Oct 2020 14:20:44
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:58:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 18:47:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 18:47:18
Data point term sent to Coder	System	05 Oct 2020 18:46:02
User entered 'right miniscus repair'	Jacob sekinger (b) (4) (b) (4)	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 2019'	Jacob sekinger (b) (4)	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 2019'	Jacob sekinger (b) (4)	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2019'	System	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2019'	System	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2019'	System	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2019'	System	05 Oct 2020 18:45:27

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:06:53
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'no known underlying condition which led to this procedure, probably caused by age' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	28 Oct 2020 14:21:41
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 03:58:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:50:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 00:50:25
Data point term sent to Coder	System	05 Oct 2020 18:47:03
User entered 'left miniscus repair'	Jacob sekinger (b) (4) (b) (4)	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 2015'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 2015'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2015'	System	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2015'	System	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2015'	System	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2015'	System	05 Oct 2020 18:46:18

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 09:04:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 09:04:33
Data point term sent to Coder	System	05 Oct 2020 18:47:06
User entered 'subluxion repair - right shoulder'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 1990'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'un UNK 1990'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 1990'	System	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '1990'	System	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 1990'	System	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '1990'	System	05 Oct 2020 18:46:58

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 05:14:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 05:14:29
Data point term sent to Coder	System	05 Nov 2020 14:24:49
User entered 'BACKPAIN / MUSCLE SPASMS (2DEGREES) TO SHOULDER REPAIR'	Melissa Fuson (b) (4)	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'UN UNK 1990'	Melissa Fuson (b) (4)	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Melissa Fuson (b) (4)	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	Melissa Fuson (b) (4)	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Melissa Fuson (b) (4)	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 1990'	System	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '1990'	System	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	05 Nov 2020 14:24:44

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:48:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:48:43
Data point term sent to Coder	System	08 Dec 2020 18:48:04
User entered 'PLANTAR FASCIITIS'	Melissa Fuson (b) (4)	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'UN UNK 2000'	Melissa Fuson (b) (4)	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'Jan 2000'	System	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '2000'	System	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered empty.	System	08 Dec 2020 18:47:46

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '09:00'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered '30 Jul 2020 09:00'	System	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '195.5' cm	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:09
DataPoint set to visible.	System	30 Jul 2020 13:47:21

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '98.3' kg	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:09
DataPoint set to visible.	System	30 Jul 2020 13:47:21

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
Amendment Manager: User entered '25.71935'	System	16 Sep 2020 23:38:38
User entered '25.7'	System	05 Aug 2020 18:19:09
DataPoint set to visible.	System	30 Jul 2020 13:47:21

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'kg/m2'	System	05 Aug 2020 18:19:09
DataPoint set to visible.	System	30 Jul 2020 13:47:21

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 16:34:41
User entered '36.6' C	(b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:30:02
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:35:17
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 16:34:41
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:34:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 16:34:41
User entered '60'	(b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'bpm'	System	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 16:34:41
User entered '18'	(b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'breaths/min'	System	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 16:34:41
User entered '118'	(b) (4), (b) (6)	05 Aug 2020 18:19:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'mmHg'	System	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 16:34:41
User entered '78'	(b) (4), (b) (6)	05 Aug 2020 18:19:09

US3412030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User entered 'mmHg'	System	05 Aug 2020 18:19:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16

US3412030

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:21

US3412030

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:57:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	27 Aug 2020 12:28:47
User entered '30 Jul 2020'	(b) (4), (b) (6)	05 Aug 2020 18:19:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

[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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

[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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	15 Sep 2020 14:42:28
User entered '0' reason for change: Data Entry Error	Jacob sekinger (b) (4)	15 Sep 2020 14:42:28
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	15 Sep 2020 14:40:14
User entered '1'	(b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

[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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '1' reason for change: Data Entry Error	(b) (4)	15 Sep 2020 14:40:14
User entered '0'	Jacob sekinger (b) (4)	05 Aug 2020 18:19:47
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:38:16
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:38
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:19:47

US3412030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:48:06

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:48:06

US3412030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:48:06

US3412030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'VISIT1'	System	30 Jul 2020 13:48:06

US3412030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 13:39:31

US3412030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:20:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:20:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 13:39:31
User entered '100237' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 13:39:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 13:39:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

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)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

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)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:04

US3412030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:04

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Pre-Dose (PREDOSE)'		05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 Jul 2020' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:21:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '09:00' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:21:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '30 Jul 2020 09:00'	System	20 Aug 2020 16:50:33
User entered empty.	System	05 Aug 2020 18:21:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '36.6' C reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:21:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:21:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '60' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'bpm'	System	20 Aug 2020 16:50:33
User entered empty.	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '18' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'breaths/min'	System	20 Aug 2020 16:50:33
User entered empty.	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '118' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	20 Aug 2020 16:50:33
User entered empty.	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '78' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 16:50:33
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	20 Aug 2020 16:50:33
User entered empty.	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Post-Dose (POSTDOSE)'		05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:05:23
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, post dose vitals were taken 30 after injection' (Site from System).		11 Aug 2020 15:05:29
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 18:21:57
User entered '10:17'	(b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '30 Jul 2020 10:17'	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User closed query 'Per CDM: Please indicate if this value should be considered as CS/NCS. If CS, report as AE as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 08:54:57
Query 'Per CDM: Please indicate if this value should be considered as CS/NCS. If CS, report as AE as appropriate.' answered with 'NCS' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Oct 2020 15:08:40
User opened query 'Per CDM: Please indicate if this value should be considered as CS/NCS. If CS, report as AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 06:04:39
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 04:44:49
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'AS PER PROTOCOL TEMP IS WITHIN RANGE ' (Site from System).	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:37:43
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:38:38
User entered '95.6' F	(b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '52'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'bpm'	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '18'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'breaths/min'	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '116'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	05 Aug 2020 18:21:57

US3412030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:10

US3412030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:10

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'MRNA-1273 OR PLACEBO'	System	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '09:45'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '30 Jul 2020 09:45'	System	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'ONCE'	System	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'INTRAMUSCULAR'	System	30 Jul 2020 13:49:19

US3412030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:03

US3412030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:03

US3412030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '09:29'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:21:03

US3412030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '30 Jul 2020 09:29'	System	05 Aug 2020 18:21:03

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '30 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '09:32'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '30 Jul 2020 09:32'	System	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	05 Aug 2020 18:20:49

US3412030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 18:20:25

US3412030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	05 Aug 2020 18:20:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:23:18', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '758b0833-e53a-46f3-80d8-f3f12f189f31'	System	30 Jul 2020 14:23:50
User entered 'Yes (Y)'	System	30 Jul 2020 14:23:50

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:23:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '758b0833-e53a-46f3-80d8-f3f12f189f31'	System	30 Jul 2020 14:23:50
User entered '95.6'	System	30 Jul 2020 14:23:50

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:23:43', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '758b0833-e53a-46f3-80d8-f3f12f189f31'	System	30 Jul 2020 14:23:50
User entered 'No (N)'	System	30 Jul 2020 14:23:50

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:23:49', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '758b0833-e53a-46f3-80d8-f3f12f189f31'	System	30 Jul 2020 14:23:50
User entered '30 Jul 2020 10:23'	System	30 Jul 2020 14:23:50

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 10:05'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 12:35'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:30:34', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '91a13f19-6647-4528-8b7f-2dc66783114f'	System	31 Jul 2020 01:30:54
User entered 'Yes (Y)'	System	31 Jul 2020 01:30:54

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:30:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '91a13f19-6647-4528-8b7f-2dc66783114f'	System	31 Jul 2020 01:30:54
User entered '97.2'	System	31 Jul 2020 01:30:54

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:30:48', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '91a13f19-6647-4528-8b7f-2dc66783114f'	System	31 Jul 2020 01:30:54
User entered 'No (N)'	System	31 Jul 2020 01:30:54

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:30:53', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '91a13f19-6647-4528-8b7f-2dc66783114f'	System	31 Jul 2020 01:30:54
User entered '30 Jul 2020 21:30'	System	31 Jul 2020 01:30:54

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 13:30'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 2'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 3'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:18', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '4a107539-bbb4-4df5-8d43-8e83aaf6bb5a'	System	02 Aug 2020 01:08:32
User entered 'Yes (Y)'	System	02 Aug 2020 01:08:32

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '4a107539-bbb4-4df5-8d43-8e83aaf6bb5a'	System	02 Aug 2020 01:08:32
User entered '95.2'	System	02 Aug 2020 01:08:32

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:28', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '4a107539-bbb4-4df5-8d43-8e83aaf6bb5a'	System	02 Aug 2020 01:08:32
User entered 'No (N)'	System	02 Aug 2020 01:08:32

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:31', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '4a107539-bbb4-4df5-8d43-8e83aaf6bb5a'	System	02 Aug 2020 01:08:32
User entered '01 Aug 2020 21:08'	System	02 Aug 2020 01:08:32

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 4'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:22:52', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b4c11f41-2755-46b8-8ecd-e65a25a4edd7'	System	03 Aug 2020 00:23:06
User entered 'Yes (Y)'	System	03 Aug 2020 00:23:06

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:22:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b4c11f41-2755-46b8-8ecd-e65a25a4edd7'	System	03 Aug 2020 00:23:06
User entered '98.2'	System	03 Aug 2020 00:23:06

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:02', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b4c11f41-2755-46b8-8ecd-e65a25a4edd7'	System	03 Aug 2020 00:23:06
User entered 'No (N)'	System	03 Aug 2020 00:23:06

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b4c11f41-2755-46b8-8ecd-e65a25a4edd7'	System	03 Aug 2020 00:23:06
User entered '02 Aug 2020 20:23'	System	03 Aug 2020 00:23:06

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 5'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:17:35', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f8d14b4b-f1ba-4510-99d6-fe47fa207d96'	System	04 Aug 2020 00:18:10
User entered 'Yes (Y)'	System	04 Aug 2020 00:18:10

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:17:40', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f8d14b4b-f1ba-4510-99d6-fe47fa207d96'	System	04 Aug 2020 00:18:10
User entered '98.3'	System	04 Aug 2020 00:18:10

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:17:47', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f8d14b4b-f1ba-4510-99d6-fe47fa207d96'	System	04 Aug 2020 00:18:10
User entered 'Yes (Y)'	System	04 Aug 2020 00:18:10

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however Prior/Concomitant Medication page is not completed. Please complete page or provide explanation. ' canceled (Site from DM). User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however Prior/Concomitant Medication page is not completed. Please complete page or provide explanation. ' (Site from DM).		28 Aug 2020 10:16:00
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).		13 Aug 2020 17:47:21
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 'contacted subject, obtained details' (Site from System).		13 Aug 2020 17:47:00
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).		11 Aug 2020 19:34:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:17:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f8d14b4b-f1ba-4510-99d6-fe47fa207d96'	System	04 Aug 2020 00:18:10
User entered '1'	System	04 Aug 2020 00:18:10

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:17:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f8d14b4b-f1ba-4510-99d6-fe47fa207d96'	System	04 Aug 2020 00:18:10
User entered '0'	System	04 Aug 2020 00:18:10

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:09', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f8d14b4b-f1ba-4510-99d6-fe47fa207d96'	System	04 Aug 2020 00:18:10
User entered '03 Aug 2020 20:18'	System	04 Aug 2020 00:18:10

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 6'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:01:56', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '31d55cbe-cc6b-4e68-9957-dc546e5147d3'	System	05 Aug 2020 02:02:16
User entered 'Yes (Y)'	System	05 Aug 2020 02:02:16

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '31d55cbe-cc6b-4e68-9957-dc546e5147d3'	System	05 Aug 2020 02:02:16
User entered '98.2'	System	05 Aug 2020 02:02:16

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:08', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '31d55cbe-cc6b-4e68-9957-dc546e5147d3'	System	05 Aug 2020 02:02:16
User entered 'No (N)'	System	05 Aug 2020 02:02:16

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:13', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '31d55cbe-cc6b-4e68-9957-dc546e5147d3'	System	05 Aug 2020 02:02:16
User entered '04 Aug 2020 22:02'	System	05 Aug 2020 02:02:16

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 7'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:04', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c1abfa80-33ed-4cb1-bc91-d20b468a7b33'	System	06 Aug 2020 00:15:30
User entered 'Yes (Y)'	System	06 Aug 2020 00:15:30

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:18', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c1abfa80-33ed-4cb1-bc91-d20b468a7b33'	System	06 Aug 2020 00:15:30
User entered '98.2'	System	06 Aug 2020 00:15:30

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:21', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c1abfa80-33ed-4cb1-bc91-d20b468a7b33'	System	06 Aug 2020 00:15:30
User entered 'No (N)'	System	06 Aug 2020 00:15:30

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:28', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c1abfa80-33ed-4cb1-bc91-d20b468a7b33'	System	06 Aug 2020 00:15:30
User entered '05 Aug 2020 20:15'	System	06 Aug 2020 00:15:30

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:04', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '12e288bc-58c4-4959-82d5-d96defeffcd8'	System	30 Jul 2020 14:24:33
User entered 'None (1)'	System	30 Jul 2020 14:24:33

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:10', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '12e288bc-58c4-4959-82d5-d96defeffcd8'	System	30 Jul 2020 14:24:33
User entered 'No (N)'	System	30 Jul 2020 14:24:33

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:14', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '12e288bc-58c4-4959-82d5-d96defeffcd8'	System	30 Jul 2020 14:24:33
User entered 'No (N)'	System	30 Jul 2020 14:24:33

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:23', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '12e288bc-58c4-4959-82d5-d96defeffcd8'	System	30 Jul 2020 14:24:33
User entered 'None (1)'	System	30 Jul 2020 14:24:33

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:30', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '12e288bc-58c4-4959-82d5-d96defeffcd8'	System	30 Jul 2020 14:24:33
User entered '30 Jul 2020 10:24'	System	30 Jul 2020 14:24:33

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 10:05'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 12:35'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:30:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '370c76fd-1f66-4d01-939a-054915a5ee14'	System	31 Jul 2020 01:31:22
User entered 'None (1)'	System	31 Jul 2020 01:31:22

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:07', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '370c76fd-1f66-4d01-939a-054915a5ee14'	System	31 Jul 2020 01:31:22
User entered 'No (N)'	System	31 Jul 2020 01:31:22

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:12', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '370c76fd-1f66-4d01-939a-054915a5ee14'	System	31 Jul 2020 01:31:22
User entered 'No (N)'	System	31 Jul 2020 01:31:22

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '370c76fd-1f66-4d01-939a-054915a5ee14'	System	31 Jul 2020 01:31:22
User entered 'None (1)'	System	31 Jul 2020 01:31:22

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:20', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '370c76fd-1f66-4d01-939a-054915a5ee14'	System	31 Jul 2020 01:31:22
User entered '30 Jul 2020 21:31'	System	31 Jul 2020 01:31:22

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 13:30'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 2'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 3'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:37', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af4242ca-a52d-46d4-81dd-ecbdf26b0450'	System	02 Aug 2020 01:08:53
User entered 'None (1)'	System	02 Aug 2020 01:08:53

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:40', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af4242ca-a52d-46d4-81dd-ecbdf26b0450'	System	02 Aug 2020 01:08:53
User entered 'No (N)'	System	02 Aug 2020 01:08:53

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:43', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af4242ca-a52d-46d4-81dd-ecbdf26b0450'	System	02 Aug 2020 01:08:53
User entered 'No (N)'	System	02 Aug 2020 01:08:53

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:47', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af4242ca-a52d-46d4-81dd-ecbdf26b0450'	System	02 Aug 2020 01:08:53
User entered 'None (1)'	System	02 Aug 2020 01:08:53

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:51', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af4242ca-a52d-46d4-81dd-ecbdf26b0450'	System	02 Aug 2020 01:08:53
User entered '01 Aug 2020 21:08'	System	02 Aug 2020 01:08:53

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 4'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:14', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '61788407-419a-4238-8d38-5806c68d6464'	System	03 Aug 2020 00:23:32
User entered 'None (1)'	System	03 Aug 2020 00:23:32

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '61788407-419a-4238-8d38-5806c68d6464'	System	03 Aug 2020 00:23:32
User entered 'No (N)'	System	03 Aug 2020 00:23:32

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:20', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '61788407-419a-4238-8d38-5806c68d6464'	System	03 Aug 2020 00:23:32
User entered 'No (N)'	System	03 Aug 2020 00:23:32

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '61788407-419a-4238-8d38-5806c68d6464'	System	03 Aug 2020 00:23:32
User entered 'None (1)'	System	03 Aug 2020 00:23:32

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '61788407-419a-4238-8d38-5806c68d6464'	System	03 Aug 2020 00:23:32
User entered '02 Aug 2020 20:23'	System	03 Aug 2020 00:23:32

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 5'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:13', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd07f5e-f352-4990-aa64-37f3b9a245bc'	System	04 Aug 2020 00:18:41
User entered 'None (1)'	System	04 Aug 2020 00:18:41

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:21', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd07f5e-f352-4990-aa64-37f3b9a245bc'	System	04 Aug 2020 00:18:41
User entered 'No (N)'	System	04 Aug 2020 00:18:41

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:26', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd07f5e-f352-4990-aa64-37f3b9a245bc'	System	04 Aug 2020 00:18:41
User entered 'No (N)'	System	04 Aug 2020 00:18:41

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:29', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd07f5e-f352-4990-aa64-37f3b9a245bc'	System	04 Aug 2020 00:18:41
User entered 'None (1)'	System	04 Aug 2020 00:18:41

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:38', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd07f5e-f352-4990-aa64-37f3b9a245bc'	System	04 Aug 2020 00:18:41
User entered '03 Aug 2020 20:18'	System	04 Aug 2020 00:18:41

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 6'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:18', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8c948ba5-affd-4e12-823b-180579f60b04'	System	05 Aug 2020 02:02:35
User entered 'None (1)'	System	05 Aug 2020 02:02:35

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:21', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8c948ba5-affd-4e12-823b-180579f60b04'	System	05 Aug 2020 02:02:35
User entered 'No (N)'	System	05 Aug 2020 02:02:35

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8c948ba5-affd-4e12-823b-180579f60b04'	System	05 Aug 2020 02:02:35
User entered 'No (N)'	System	05 Aug 2020 02:02:35

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8c948ba5-affd-4e12-823b-180579f60b04'	System	05 Aug 2020 02:02:35
User entered 'None (1)'	System	05 Aug 2020 02:02:35

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:33', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8c948ba5-affd-4e12-823b-180579f60b04'	System	05 Aug 2020 02:02:35
User entered '04 Aug 2020 22:02'	System	05 Aug 2020 02:02:35

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 7'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:46', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bd182527-8782-418b-b026-f9facb7f2c00'	System	06 Aug 2020 00:16:07
User entered 'None (1)'	System	06 Aug 2020 00:16:07

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:49', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bd182527-8782-418b-b026-f9facb7f2c00'	System	06 Aug 2020 00:16:07
User entered 'No (N)'	System	06 Aug 2020 00:16:07

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:15:58', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bd182527-8782-418b-b026-f9facb7f2c00'	System	06 Aug 2020 00:16:07
User entered 'No (N)'	System	06 Aug 2020 00:16:07

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bd182527-8782-418b-b026-f9facb7f2c00'	System	06 Aug 2020 00:16:07
User entered 'None (1)'	System	06 Aug 2020 00:16:07

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bd182527-8782-418b-b026-f9facb7f2c00'	System	06 Aug 2020 00:16:07
User entered '05 Aug 2020 20:16'	System	06 Aug 2020 00:16:07

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:37', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'None (0)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'None (0)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'None (0)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:47', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'None (0)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:50', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'None (0)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:53', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'None (0)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:24:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered 'No (N)'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T10:25:03', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '1de95339-0a64-405e-a0a4-629829defef4'	System	30 Jul 2020 14:25:16
User entered '30 Jul 2020 10:25'	System	30 Jul 2020 14:25:16

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 10:05'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 12:35'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:33', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'None (0)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:37', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'None (0)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'None (0)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'None (0)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:48', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'None (0)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:52', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'None (0)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:31:58', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered 'No (N)'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-07-30T21:32:02', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'af835221-5c48-43b2-8391-87d4c72ebc18'	System	31 Jul 2020 01:32:06
User entered '30 Jul 2020 21:32'	System	31 Jul 2020 01:32:06

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Jul 2020 13:30'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 2'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 3'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:08:56', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'None (0)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:01', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'None (0)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'None (0)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:09', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'None (0)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:12', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'None (0)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:15', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'None (0)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:19', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered 'No (N)'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-01T21:09:22', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e276664f-d3f0-4285-bb9e-ec7d485a13f3'	System	02 Aug 2020 01:09:24
User entered '01 Aug 2020 21:09'	System	02 Aug 2020 01:09:24

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 4'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:32', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'None (0)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:36', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'None (0)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'None (0)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'None (0)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:45', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'None (0)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:47', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'None (0)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:51', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered 'No (N)'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-02T20:23:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df6a47c2-522c-483b-b0c4-f8e7397d5062'	System	03 Aug 2020 00:23:57
User entered '02 Aug 2020 20:23'	System	03 Aug 2020 00:23:57

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 5'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:47', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'None (0)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:18:52', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'None (0)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:19:35', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'None (0)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:19:43', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'No interference with activity (1)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:19:16', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'None (0)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:19:22', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'None (0)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:19:26', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered 'No (N)'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-03T20:19:52', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '9676a6e9-d0ba-49d4-ab49-b1d142c4cce0'	System	04 Aug 2020 00:19:55
User entered '03 Aug 2020 20:19'	System	04 Aug 2020 00:19:55

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 6'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:38', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'None (0)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'None (0)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'None (0)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:47', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'None (0)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:50', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'None (0)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'None (0)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered 'No (N)'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-04T22:02:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'e8692f38-7e8b-4150-bfaf-d08cf62a0ed2'	System	05 Aug 2020 02:03:01
User entered '04 Aug 2020 22:02'	System	05 Aug 2020 02:03:01

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 7'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:15', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'None (0)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:19', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'None (0)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:28', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'None (0)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:31', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'None (0)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:45', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'None (0)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:48', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'None (0)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered 'No (N)'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-05T20:16:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd5e97f02-dc04-49a1-b2ed-5b51903627ff'	System	06 Aug 2020 00:16:58
User entered '05 Aug 2020 20:16'	System	06 Aug 2020 00:16:58

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 13:49:19

US3412030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:24:17

US3412030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered '06 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:24:17

US3412030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4)	15 Sep 2020 13:24:17

US3412030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 13:24:17

US3412030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:27:46

US3412030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	27 Aug 2020 12:27:46

US3412030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:24:41

US3412030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered '13 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:24:41

US3412030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4)	15 Sep 2020 13:24:41

US3412030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 13:24:41

US3412030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:28:01

US3412030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	27 Aug 2020 12:28:01

US3412030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Sep 2020 17:57:14

US3412030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered '20 Aug 2020'	Mason Urban (b) (4)	10 Sep 2020 17:57:14

US3412030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	10 Sep 2020 17:57:14

US3412030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered empty.	Mason Urban (b) (4)	10 Sep 2020 17:57:14

US3412030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:28:18

US3412030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	27 Aug 2020 12:28:18

US3412030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:28:47

US3412030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:28:47

US3412030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:28:47

US3412030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'VISIT2'	System	27 Aug 2020 12:28:47

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '07:42'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '27 Aug 2020 07:42'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '36.4' C	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '68'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'bpm'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '16'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'breaths/min'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '112'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '74'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '09:02'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '27 Aug 2020 09:02'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '97.6' F	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '50'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'bpm'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '14'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'breaths/min'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '118'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '76'	Jacob sekinger (b) (4)	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'mmHg'	System	15 Sep 2020 13:33:27

US3412030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:34:05

US3412030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:34:05

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '08:25'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '27 Aug 2020 08:25'	System	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'ONCE'	System	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 12:31:32

US3412030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:19

US3412030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:19

US3412030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '08:13'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:19

US3412030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '27 Aug 2020 08:13'	System	15 Sep 2020 13:35:19

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '27 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '08:17'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '27 Aug 2020 08:17'	System	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	15 Sep 2020 13:35:42

US3412030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:59:09

US3412030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	03 Sep 2020 18:59:09

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:04:45', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '2f50ace1-d22a-4e9a-bb88-c4fc071ca224'	System	27 Aug 2020 13:05:04
User entered 'Yes (Y)'	System	27 Aug 2020 13:05:04

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:04:50', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '2f50ace1-d22a-4e9a-bb88-c4fc071ca224'	System	27 Aug 2020 13:05:04
User entered '97.6'	System	27 Aug 2020 13:05:04

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:04:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '2f50ace1-d22a-4e9a-bb88-c4fc071ca224'	System	27 Aug 2020 13:05:04
User entered 'No (N)'	System	27 Aug 2020 13:05:04

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:04:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '2f50ace1-d22a-4e9a-bb88-c4fc071ca224'	System	27 Aug 2020 13:05:04
User entered '27 Aug 2020 09:04'	System	27 Aug 2020 13:05:04

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 08:45'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 11:15'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd2e17ff0-386d-401b-a5eb-e526f788d018'	System	28 Aug 2020 01:49:31
User entered 'Yes (Y)'	System	28 Aug 2020 01:49:31

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:22', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd2e17ff0-386d-401b-a5eb-e526f788d018'	System	28 Aug 2020 01:49:31
User entered '97.0'	System	28 Aug 2020 01:49:31

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:25', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd2e17ff0-386d-401b-a5eb-e526f788d018'	System	28 Aug 2020 01:49:31
User entered 'No (N)'	System	28 Aug 2020 01:49:31

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:28', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd2e17ff0-386d-401b-a5eb-e526f788d018'	System	28 Aug 2020 01:49:31
User entered '27 Aug 2020 21:49'	System	28 Aug 2020 01:49:31

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 12:10'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 2'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:03', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3bfbb29e-b470-4720-92c4-826ebdcdae14'	System	29 Aug 2020 00:02:20
User entered 'Yes (Y)'	System	29 Aug 2020 00:02:20

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:08', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3bfbb29e-b470-4720-92c4-826ebdcdae14'	System	29 Aug 2020 00:02:20
User entered '97.2'	System	29 Aug 2020 00:02:20

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:11', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3bfbb29e-b470-4720-92c4-826ebdcdae14'	System	29 Aug 2020 00:02:20
User entered 'No (N)'	System	29 Aug 2020 00:02:20

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3bfbb29e-b470-4720-92c4-826ebdcdae14'	System	29 Aug 2020 00:02:20
User entered '28 Aug 2020 20:02'	System	29 Aug 2020 00:02:20

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 3'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:13:32', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f29e8d65-dba5-4439-a8a7-1cf044218814'	System	29 Aug 2020 19:14:41
User entered 'Yes (Y)'	System	29 Aug 2020 19:14:41

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:13:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f29e8d65-dba5-4439-a8a7-1cf044218814'	System	29 Aug 2020 19:14:41
User entered '95.6'	System	29 Aug 2020 19:14:41

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:14:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f29e8d65-dba5-4439-a8a7-1cf044218814'	System	29 Aug 2020 19:14:41
User entered 'No (N)'	System	29 Aug 2020 19:14:41

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:14:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f29e8d65-dba5-4439-a8a7-1cf044218814'	System	29 Aug 2020 19:14:41
User entered '29 Aug 2020 15:14'	System	29 Aug 2020 19:14:41

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 4'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:00:49', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df50044e-9298-4e20-9754-7b39ccb5668c'	System	31 Aug 2020 00:01:06
User entered 'Yes (Y)'	System	31 Aug 2020 00:01:06

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:00:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df50044e-9298-4e20-9754-7b39ccb5668c'	System	31 Aug 2020 00:01:06
User entered '97.4'	System	31 Aug 2020 00:01:06

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:00:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df50044e-9298-4e20-9754-7b39ccb5668c'	System	31 Aug 2020 00:01:06
User entered 'No (N)'	System	31 Aug 2020 00:01:06

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'df50044e-9298-4e20-9754-7b39ccb5668c'	System	31 Aug 2020 00:01:06
User entered '30 Aug 2020 20:01'	System	31 Aug 2020 00:01:06

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 5'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:25', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '13c36fb6-edb2-40b7-9423-2b9219921b19'	System	01 Sep 2020 11:03:42
User entered 'Yes (Y)'	System	01 Sep 2020 11:03:42

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:34', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '13c36fb6-edb2-40b7-9423-2b9219921b19'	System	01 Sep 2020 11:03:42
User entered '96.6'	System	01 Sep 2020 11:03:42

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:37', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '13c36fb6-edb2-40b7-9423-2b9219921b19'	System	01 Sep 2020 11:03:42
User entered 'No (N)'	System	01 Sep 2020 11:03:42

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:40', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '13c36fb6-edb2-40b7-9423-2b9219921b19'	System	01 Sep 2020 11:03:42
User entered '01 Sep 2020 07:03'	System	01 Sep 2020 11:03:42

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 6'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:00:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'fc146001-279c-4444-bff2-497bcf4208ab'	System	02 Sep 2020 12:01:09
User entered 'Yes (Y)'	System	02 Sep 2020 12:01:09

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:00:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'fc146001-279c-4444-bff2-497bcf4208ab'	System	02 Sep 2020 12:01:09
User entered '98.2'	System	02 Sep 2020 12:01:09

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:03', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'fc146001-279c-4444-bff2-497bcf4208ab'	System	02 Sep 2020 12:01:09
User entered 'No (N)'	System	02 Sep 2020 12:01:09

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:06', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'fc146001-279c-4444-bff2-497bcf4208ab'	System	02 Sep 2020 12:01:09
User entered '02 Sep 2020 08:01'	System	02 Sep 2020 12:01:09

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 7'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:09', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '24377c51-a5f1-4791-a6a0-0c9c975a6af3'	System	02 Sep 2020 23:50:29
User entered 'Yes (Y)'	System	02 Sep 2020 23:50:29

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '24377c51-a5f1-4791-a6a0-0c9c975a6af3'	System	02 Sep 2020 23:50:29
User entered '98.2'	System	02 Sep 2020 23:50:29

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:20', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '24377c51-a5f1-4791-a6a0-0c9c975a6af3'	System	02 Sep 2020 23:50:29
User entered 'No (N)'	System	02 Sep 2020 23:50:29

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:26', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '24377c51-a5f1-4791-a6a0-0c9c975a6af3'	System	02 Sep 2020 23:50:29
User entered '02 Sep 2020 19:50'	System	02 Sep 2020 23:50:29

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eada51d8-bc66-4fb0-9d65-e4f7cee61b0d'	System	27 Aug 2020 13:05:24
User entered 'None (1)'	System	27 Aug 2020 13:05:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:09', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eada51d8-bc66-4fb0-9d65-e4f7cee61b0d'	System	27 Aug 2020 13:05:24
User entered 'No (N)'	System	27 Aug 2020 13:05:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:12', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eada51d8-bc66-4fb0-9d65-e4f7cee61b0d'	System	27 Aug 2020 13:05:24
User entered 'No (N)'	System	27 Aug 2020 13:05:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eada51d8-bc66-4fb0-9d65-e4f7cee61b0d'	System	27 Aug 2020 13:05:24
User entered 'None (1)'	System	27 Aug 2020 13:05:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:21', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eada51d8-bc66-4fb0-9d65-e4f7cee61b0d'	System	27 Aug 2020 13:05:24
User entered '27 Aug 2020 09:05'	System	27 Aug 2020 13:05:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 08:45'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 11:15'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:32', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0e499348-0ace-4f22-970a-baea6f75f31e'	System	28 Aug 2020 01:49:46
User entered 'None (1)'	System	28 Aug 2020 01:49:46

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:35', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0e499348-0ace-4f22-970a-baea6f75f31e'	System	28 Aug 2020 01:49:46
User entered 'No (N)'	System	28 Aug 2020 01:49:46

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:38', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0e499348-0ace-4f22-970a-baea6f75f31e'	System	28 Aug 2020 01:49:46
User entered 'No (N)'	System	28 Aug 2020 01:49:46

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0e499348-0ace-4f22-970a-baea6f75f31e'	System	28 Aug 2020 01:49:46
User entered 'None (1)'	System	28 Aug 2020 01:49:46

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:45', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0e499348-0ace-4f22-970a-baea6f75f31e'	System	28 Aug 2020 01:49:46
User entered '27 Aug 2020 21:49'	System	28 Aug 2020 01:49:46

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 12:10'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 2'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:21', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '95624b51-0d90-44fa-bc4d-ff1b8b50dd22'	System	29 Aug 2020 00:02:40
User entered 'None (1)'	System	29 Aug 2020 00:02:40

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '95624b51-0d90-44fa-bc4d-ff1b8b50dd22'	System	29 Aug 2020 00:02:40
User entered 'No (N)'	System	29 Aug 2020 00:02:40

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '95624b51-0d90-44fa-bc4d-ff1b8b50dd22'	System	29 Aug 2020 00:02:40
User entered 'No (N)'	System	29 Aug 2020 00:02:40

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:30', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '95624b51-0d90-44fa-bc4d-ff1b8b50dd22'	System	29 Aug 2020 00:02:40
User entered 'None (1)'	System	29 Aug 2020 00:02:40

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:33', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '95624b51-0d90-44fa-bc4d-ff1b8b50dd22'	System	29 Aug 2020 00:02:40
User entered '28 Aug 2020 20:02'	System	29 Aug 2020 00:02:40

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 3'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:14:43', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eee102bc-6e1f-4cd5-87af-8026bd8fc484'	System	29 Aug 2020 19:15:07
User entered 'None (1)'	System	29 Aug 2020 19:15:07

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:14:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eee102bc-6e1f-4cd5-87af-8026bd8fc484'	System	29 Aug 2020 19:15:07
User entered 'No (N)'	System	29 Aug 2020 19:15:07

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:14:58', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eee102bc-6e1f-4cd5-87af-8026bd8fc484'	System	29 Aug 2020 19:15:07
User entered 'No (N)'	System	29 Aug 2020 19:15:07

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:03', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eee102bc-6e1f-4cd5-87af-8026bd8fc484'	System	29 Aug 2020 19:15:07
User entered 'None (1)'	System	29 Aug 2020 19:15:07

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:06', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'eee102bc-6e1f-4cd5-87af-8026bd8fc484'	System	29 Aug 2020 19:15:07
User entered '29 Aug 2020 15:15'	System	29 Aug 2020 19:15:07

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 4'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:04', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3fbc81a8-7d74-482c-9d82-aa7f88d5cb71'	System	31 Aug 2020 00:01:21
User entered 'None (1)'	System	31 Aug 2020 00:01:21

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:07', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3fbc81a8-7d74-482c-9d82-aa7f88d5cb71'	System	31 Aug 2020 00:01:21
User entered 'No (N)'	System	31 Aug 2020 00:01:21

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:10', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3fbc81a8-7d74-482c-9d82-aa7f88d5cb71'	System	31 Aug 2020 00:01:21
User entered 'No (N)'	System	31 Aug 2020 00:01:21

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:12', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3fbc81a8-7d74-482c-9d82-aa7f88d5cb71'	System	31 Aug 2020 00:01:21
User entered 'None (1)'	System	31 Aug 2020 00:01:21

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3fbc81a8-7d74-482c-9d82-aa7f88d5cb71'	System	31 Aug 2020 00:01:21
User entered '30 Aug 2020 20:01'	System	31 Aug 2020 00:01:21

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 5'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd0579ac8-4f9e-4817-90ef-8712f6e86bc2'	System	01 Sep 2020 11:03:57
User entered 'None (1)'	System	01 Sep 2020 11:03:57

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:46', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd0579ac8-4f9e-4817-90ef-8712f6e86bc2'	System	01 Sep 2020 11:03:57
User entered 'No (N)'	System	01 Sep 2020 11:03:57

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:49', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd0579ac8-4f9e-4817-90ef-8712f6e86bc2'	System	01 Sep 2020 11:03:57
User entered 'No (N)'	System	01 Sep 2020 11:03:57

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:51', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd0579ac8-4f9e-4817-90ef-8712f6e86bc2'	System	01 Sep 2020 11:03:57
User entered 'None (1)'	System	01 Sep 2020 11:03:57

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd0579ac8-4f9e-4817-90ef-8712f6e86bc2'	System	01 Sep 2020 11:03:57
User entered '01 Sep 2020 07:03'	System	01 Sep 2020 11:03:57

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 6'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:10', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6b81583e-c0e9-4990-86d0-dabcd7d1c19e'	System	02 Sep 2020 12:01:24
User entered 'None (1)'	System	02 Sep 2020 12:01:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:12', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6b81583e-c0e9-4990-86d0-dabcd7d1c19e'	System	02 Sep 2020 12:01:24
User entered 'No (N)'	System	02 Sep 2020 12:01:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:15', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6b81583e-c0e9-4990-86d0-dabcd7d1c19e'	System	02 Sep 2020 12:01:24
User entered 'No (N)'	System	02 Sep 2020 12:01:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6b81583e-c0e9-4990-86d0-dabcd7d1c19e'	System	02 Sep 2020 12:01:24
User entered 'None (1)'	System	02 Sep 2020 12:01:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:20', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6b81583e-c0e9-4990-86d0-dabcd7d1c19e'	System	02 Sep 2020 12:01:24
User entered '02 Sep 2020 08:01'	System	02 Sep 2020 12:01:24

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 7'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:32', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0c6aa4a3-8cc6-4a41-ab99-f0d3ffce2ef2'	System	02 Sep 2020 23:51:20
User entered 'None (1)'	System	02 Sep 2020 23:51:20

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0c6aa4a3-8cc6-4a41-ab99-f0d3ffce2ef2'	System	02 Sep 2020 23:51:20
User entered 'No (N)'	System	02 Sep 2020 23:51:20

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:50:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0c6aa4a3-8cc6-4a41-ab99-f0d3ffce2ef2'	System	02 Sep 2020 23:51:20
User entered 'No (N)'	System	02 Sep 2020 23:51:20

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:13', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0c6aa4a3-8cc6-4a41-ab99-f0d3ffce2ef2'	System	02 Sep 2020 23:51:20
User entered 'None (1)'	System	02 Sep 2020 23:51:20

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0c6aa4a3-8cc6-4a41-ab99-f0d3ffce2ef2'	System	02 Sep 2020 23:51:20
User entered '02 Sep 2020 19:51'	System	02 Sep 2020 23:51:20

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:25', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'None (0)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:28', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'None (0)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:31', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'None (0)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:35', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'None (0)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:38', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'None (0)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'None (0)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:46', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered 'No (N)'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T09:05:50', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a20ad61a-47fa-458b-9a7a-f83499e74c5c'	System	27 Aug 2020 13:05:56
User entered '27 Aug 2020 09:05'	System	27 Aug 2020 13:05:56

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 08:45'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 11:15'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:49', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'None (0)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:51', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'None (0)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'None (0)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:56', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'None (0)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:49:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'None (0)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:50:01', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'None (0)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:50:04', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered 'No (N)'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-27T21:50:08', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '844751f0-5c24-4945-9f68-d9d2214d95f1'	System	28 Aug 2020 01:50:11
User entered '27 Aug 2020 21:50'	System	28 Aug 2020 01:50:11

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '27 Aug 2020 12:10'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 2'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:03:09', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:51', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'None (0)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:55', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'None (0)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'None (0)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:02:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'None (0)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:03:02', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'None (0)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:03:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered 'No (N)'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-28T20:03:14', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8965f962-b32d-4e17-90bb-77d786607f2e'	System	29 Aug 2020 00:03:16
User entered '28 Aug 2020 20:03'	System	29 Aug 2020 00:03:16

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 3'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:10', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'None (0)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:16', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'None (0)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:18', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'None (0)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:19', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'None (0)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:21', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'None (0)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'None (0)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:26', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered 'No (N)'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-29T15:15:29', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '0bc493c7-07a1-489a-b550-11856ab50cc7'	System	29 Aug 2020 19:15:31
User entered '29 Aug 2020 15:15'	System	29 Aug 2020 19:15:31

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 4'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:22', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'None (0)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'None (0)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'None (0)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:29', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'None (0)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:32', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'None (0)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:34', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'None (0)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:37', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered 'No (N)'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-08-30T20:01:41', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd6c872cf-ef93-4821-955d-cd134f41bd90'	System	31 Aug 2020 00:01:44
User entered '30 Aug 2020 20:01'	System	31 Aug 2020 00:01:44

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 5'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'None (0)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:03:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'None (0)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:04:01', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'None (0)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:04:04', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'None (0)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:04:05', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'None (0)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:04:07', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'None (0)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:04:10', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered 'No (N)'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-01T07:04:14', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'b8191697-1aca-4e01-a353-28be606f83f7'	System	01 Sep 2020 11:04:15
User entered '01 Sep 2020 07:04'	System	01 Sep 2020 11:04:15

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 6'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'None (0)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'None (0)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:30', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'None (0)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:32', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'None (0)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:34', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'None (0)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:36', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'None (0)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered 'No (N)'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T08:01:42', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ecd83fe7-4448-459a-9cc8-60bf020c12a9'	System	02 Sep 2020 12:01:43
User entered '02 Sep 2020 08:01'	System	02 Sep 2020 12:01:43

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	27 Aug 2020 12:31:32
User entered 'Day 7'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:25', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:29', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'None (0)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:33', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'None (0)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:36', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'None (0)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'None (0)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:42', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'None (0)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:45', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered 'No (N)'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-09-02T19:51:50', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '3cdf230f-8608-4a21-9db9-9d843e8dffc8'	System	02 Sep 2020 23:51:54
User entered '02 Sep 2020 19:51'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 12:31:32

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	02 Sep 2020 23:51:54
User entered 'Day 8'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:28:51

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	02 Sep 2020 23:51:54
User entered 'Day 9'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:28:51

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:28:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	02 Sep 2020 23:51:54
User entered 'Day 8'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	02 Sep 2020 23:51:54
User entered 'Day 9'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:28:51

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:28:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:28:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:51:54

US3412030

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:28:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:51:54

US3412030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:06:47

US3412030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:06:47

US3412030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:06:47

US3412030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:06:47

US3412030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:22:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:06:52

US3412030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	03 Sep 2020 19:06:52

US3412030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Sep 2020 17:57:24

US3412030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '10 Sep 2020'	Mason Urban (b) (4)	10 Sep 2020 17:57:24

US3412030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	10 Sep 2020 17:57:24

US3412030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	Mason Urban (b) (4)	10 Sep 2020 17:57:24

US3412030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Sep 2020 17:57:28

US3412030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	10 Sep 2020 17:57:28

US3412030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 17:38:16

US3412030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered '17 Sep 2020'	Mason Urban (b) (4)	17 Sep 2020 17:38:16

US3412030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Sep 2020 17:38:16

US3412030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered empty.	Mason Urban (b) (4)	17 Sep 2020 17:38:16

US3412030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 17:38:20

US3412030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	17 Sep 2020 17:38:20

US3412030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:35

US3412030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered '25 Sep 2020'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:35

US3412030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:35

US3412030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'VISIT3'	System	29 Sep 2020 17:40:35

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered empty.	System	29 Sep 2020 17:40:49

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23

US3412030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23

US3412030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:34:21
User entered 'Yes (Y)'	Mylene Asmar-Rios	29 Sep 2020 17:41:42
	(b) (4)	

US3412030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:34:21
User entered '25 Sep 2020'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:41:42

US3412030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:42:43

US3412030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered '25 Sep 2020'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:42:43

US3412030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:18
User entered '09:22'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:42:43

US3412030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered '25 Sep 2020 09:22'	System	29 Sep 2020 17:42:43

US3412030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:42:05
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:42:52

US3412030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	29 Sep 2020 17:42:52

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 64'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '29 Sep 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '03 Oct 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 71'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-10-06T09:49:55', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a81c67c1-f351-43ff-8fd1-acb15963980a'	System	06 Oct 2020 13:50:11
User entered 'No (N)'	System	06 Oct 2020 13:50:11

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-10-06T09:50:03', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a81c67c1-f351-43ff-8fd1-acb15963980a'	System	06 Oct 2020 13:50:11
User entered 'No (N)'	System	06 Oct 2020 13:50:11

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-10-06T09:50:09', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'a81c67c1-f351-43ff-8fd1-acb15963980a'	System	06 Oct 2020 13:50:11
User entered '06 Oct 2020 09:50:09'	System	06 Oct 2020 13:50:11

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '06 Oct 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '10 Oct 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 78'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-10-13T13:52:15', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f6465986-3cc2-4b02-bf49-fc2906fcce52'	System	13 Oct 2020 17:52:39
User entered 'No (N)'	System	13 Oct 2020 17:52:39

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-10-13T13:52:27', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f6465986-3cc2-4b02-bf49-fc2906fcce52'	System	13 Oct 2020 17:52:39
User entered 'No (N)'	System	13 Oct 2020 17:52:39

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-10-13T13:52:31', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'f6465986-3cc2-4b02-bf49-fc2906fcce52'	System	13 Oct 2020 17:52:39
User entered '13 Oct 2020 13:52:31'	System	13 Oct 2020 17:52:39

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '13 Oct 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:29:25
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '17 Oct 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 92'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:28:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '27 Oct 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '31 Oct 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 99'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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US3412030

Folder: Safety Follow Up Diary (1)

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[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:28:51

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '03 Nov 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '07 Nov 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 106'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

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[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)
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Folder: Safety Follow Up Diary (1)

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[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

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[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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Folder: Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

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Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '10 Nov 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '14 Nov 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered 'Day 113'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18

US3412030

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '17 Nov 2020 00:01'	System	30 Jul 2020 13:49:19

US3412030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:23:18
Data entry locked.	System	30 Jul 2020 13:49:19
User entered '21 Nov 2020 23:59'	System	30 Jul 2020 13:49:19

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2020-11-28T17:57:57', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'dafa1bcc-ddc6-4296-a73e-d49e45ff6175'	System	28 Nov 2020 22:58:41
User entered 'No (N)'	System	28 Nov 2020 22:58:41

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2020-11-28T17:58:19', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'dafa1bcc-ddc6-4296-a73e-d49e45ff6175'	System	28 Nov 2020 22:58:41
User entered 'No (N)'	System	28 Nov 2020 22:58:41

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-11-28T17:58:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'dafa1bcc-ddc6-4296-a73e-d49e45ff6175'	System	28 Nov 2020 22:58:41
User entered '28 Nov 2020 17:58:39'	System	28 Nov 2020 22:58:41

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2020-12-05T08:24:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd4f18268-23b3-476f-9cbe-0a793d904e72'	System	05 Dec 2020 13:25:11
User entered 'No (N)'	System	05 Dec 2020 13:25:11

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2020-12-05T08:24:59', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd4f18268-23b3-476f-9cbe-0a793d904e72'	System	05 Dec 2020 13:25:11
User entered 'No (N)'	System	05 Dec 2020 13:25:11

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-12-05T08:25:08', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd4f18268-23b3-476f-9cbe-0a793d904e72'	System	05 Dec 2020 13:25:11
User entered '05 Dec 2020 08:25:08'	System	05 Dec 2020 13:25:11

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2020-12-12T07:29:42', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '46b5773e-1b8b-4cb0-8469-301520512447'	System	12 Dec 2020 12:29:49
User entered 'No (N)'	System	12 Dec 2020 12:29:49

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2020-12-12T07:29:46', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '46b5773e-1b8b-4cb0-8469-301520512447'	System	12 Dec 2020 12:29:49
User entered 'No (N)'	System	12 Dec 2020 12:29:49

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-12-12T07:29:49', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '46b5773e-1b8b-4cb0-8469-301520512447'	System	12 Dec 2020 12:29:49
User entered '12 Dec 2020 07:29:49'	System	12 Dec 2020 12:29:49

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2020-12-23T13:05:45', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8ca0e0ec-cb1e-40d6-8795-eeb34550add3'	System	23 Dec 2020 18:05:56
User entered 'No (N)'	System	23 Dec 2020 18:05:56

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2020-12-23T13:05:50', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8ca0e0ec-cb1e-40d6-8795-eeb34550add3'	System	23 Dec 2020 18:05:56
User entered 'No (N)'	System	23 Dec 2020 18:05:56

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-12-23T13:05:54', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8ca0e0ec-cb1e-40d6-8795-eeb34550add3' User entered '23 Dec 2020 13:05:54'	System	23 Dec 2020 18:05:56
	System	23 Dec 2020 18:05:56

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2020-12-26T06:40:14', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '086e3657-69c9-478f-a684-89a9102657ce'	System	26 Dec 2020 11:40:26
User entered 'No (N)'	System	26 Dec 2020 11:40:26

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2020-12-26T06:40:17', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '086e3657-69c9-478f-a684-89a9102657ce'	System	26 Dec 2020 11:40:26
User entered 'No (N)'	System	26 Dec 2020 11:40:26

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2020-12-26T06:40:23', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '086e3657-69c9-478f-a684-89a9102657ce'	System	26 Dec 2020 11:40:26
User entered '26 Dec 2020 06:40:23'	System	26 Dec 2020 11:40:26

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2021-01-02T06:22:19', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '81b2016c-2cb5-43a6-aa60-f96946e81a62'	System	02 Jan 2021 11:22:25
User entered 'No (N)'	System	02 Jan 2021 11:22:25

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2021-01-02T06:22:23', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '81b2016c-2cb5-43a6-aa60-f96946e81a62'	System	02 Jan 2021 11:22:25
User entered 'No (N)'	System	02 Jan 2021 11:22:25

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2021-01-02T06:22:26', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '81b2016c-2cb5-43a6-aa60-f96946e81a62'	System	02 Jan 2021 11:22:25
User entered '02 Jan 2021 06:22:26'	System	02 Jan 2021 11:22:25

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2021-01-09T07:43:16', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bf55d83d-4d3e-4436-b35a-9b52390fa8e1'	System	09 Jan 2021 12:44:43
User entered 'Yes (Y)'	System	09 Jan 2021 12:44:43

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2021-01-09T07:43:25', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bf55d83d-4d3e-4436-b35a-9b52390fa8e1'	System	09 Jan 2021 12:44:43
User entered 'No (N)'	System	09 Jan 2021 12:44:43

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2021-01-09T07:43:30', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bf55d83d-4d3e-4436-b35a-9b52390fa8e1'	System	09 Jan 2021 12:44:43
User entered 'No (N)'	System	09 Jan 2021 12:44:43

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2021-01-09T07:43:39', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bf55d83d-4d3e-4436-b35a-9b52390fa8e1'	System	09 Jan 2021 12:44:43
User entered 'Yes (Y)'	System	09 Jan 2021 12:44:43

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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 (cec2bdc7412af97f)', Time: '2021-01-09T07:43:46', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bf55d83d-4d3e-4436-b35a-9b52390fa8e1'	System	09 Jan 2021 12:44:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 12:44:43

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2021-01-09T07:44:33', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'bf55d83d-4d3e-4436-b35a-9b52390fa8e1'	System	09 Jan 2021 12:44:43
User entered '09 Jan 2021 07:44:33'	System	09 Jan 2021 12:44:43

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2021-01-16T09:21:29', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6c18b844-3384-441d-92f1-12d1e84d3415'	System	16 Jan 2021 14:21:38
User entered 'No (N)'	System	16 Jan 2021 14:21:38

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2021-01-16T09:21:33', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6c18b844-3384-441d-92f1-12d1e84d3415'	System	16 Jan 2021 14:21:38
User entered 'No (N)'	System	16 Jan 2021 14:21:38

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2021-01-16T09:21:36', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '6c18b844-3384-441d-92f1-12d1e84d3415'	System	16 Jan 2021 14:21:38
User entered '16 Jan 2021 09:21:36'	System	16 Jan 2021 14:21:38

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (cec2bdc7412af97f)', Time: '2021-01-23T10:27:15', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '5849eae1-c5e4-4e6d-911f-c0a5f1351751'	System	23 Jan 2021 15:27:25
User entered 'No (N)'	System	23 Jan 2021 15:27:25

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (cec2bdc7412af97f)', Time: '2021-01-23T10:27:18', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '5849eae1-c5e4-4e6d-911f-c0a5f1351751'	System	23 Jan 2021 15:27:25
User entered 'No (N)'	System	23 Jan 2021 15:27:25

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cec2bdc7412af97f)', Time: '2021-01-23T10:27:22', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '5849eae1-c5e4-4e6d-911f-c0a5f1351751' User entered '23 Jan 2021 10:27:22'	System	23 Jan 2021 15:27:25
	System	23 Jan 2021 15:27:25

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-08T10:25:44', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8153d951-6749-4afb-9e35-6d093d06ca73'	System	08 Feb 2021 15:25:58
User entered 'No (N)'	System	08 Feb 2021 15:25:58

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-08T10:25:48', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8153d951-6749-4afb-9e35-6d093d06ca73' User entered 'No (N)'	System	08 Feb 2021 15:25:58
	System	08 Feb 2021 15:25:58

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-08T10:25:56', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '8153d951-6749-4afb-9e35-6d093d06ca73' User entered '08 Feb 2021 10:25:56'	System	08 Feb 2021 15:25:58
	System	08 Feb 2021 15:25:58

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-14T19:09:08', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '38e57b12-050e-4977-9f6c-24783c2dfbc8' User entered 'No (N)'	System	15 Feb 2021 00:12:08
	System	15 Feb 2021 00:12:08

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-14T19:09:13', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '38e57b12-050e-4977-9f6c-24783c2dfbc8' User entered 'No (N)'	System	15 Feb 2021 00:12:08
	System	15 Feb 2021 00:12:08

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-14T19:09:20', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '38e57b12-050e-4977-9f6c-24783c2dfbc8' User entered '14 Feb 2021 19:09:20'	System	15 Feb 2021 00:12:08
	System	15 Feb 2021 00:12:08

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-20T20:55:11', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '181269a8-6d28-43ba-b512-dc53722e8736'	System	21 Feb 2021 01:55:31
User entered 'No (N)'	System	21 Feb 2021 01:55:31

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-20T20:55:14', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '181269a8-6d28-43ba-b512-dc53722e8736'	System	21 Feb 2021 01:55:31
User entered 'No (N)'	System	21 Feb 2021 01:55:31

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-20T20:55:24', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '181269a8-6d28-43ba-b512-dc53722e8736' User entered '20 Feb 2021 20:55:24'	System	21 Feb 2021 01:55:31
	System	21 Feb 2021 01:55:31

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-28T21:36:45-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c545bf4a-7b22-428e-b122-9d9077b0931f'	System	01 Mar 2021 02:42:30
User entered 'No (N)'	System	01 Mar 2021 02:42:30

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-28T21:36:49-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c545bf4a-7b22-428e-b122-9d9077b0931f'	System	01 Mar 2021 02:42:30
User entered 'No (N)'	System	01 Mar 2021 02:42:30

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-02-28T21:36:53-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'c545bf4a-7b22-428e-b122-9d9077b0931f' User entered '28 Feb 2021 21:36:53'	System	01 Mar 2021 02:42:30
	System	01 Mar 2021 02:42:30

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-06T15:09:30-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '887eecdc-0a61-4d04-9af7-7d9b15add4f'	System	06 Mar 2021 20:09:40
User entered 'No (N)'	System	06 Mar 2021 20:09:40

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-06T15:09:32-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '887eecdc-0a61-4d04-9af7-7d9b15add4f'	System	06 Mar 2021 20:09:40
User entered 'No (N)'	System	06 Mar 2021 20:09:40

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-06T15:09:36-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '887eecdc-0a61-4d04-9af7-7d9b15add4f'	System	06 Mar 2021 20:09:40
User entered '06 Mar 2021 15:09:36'	System	06 Mar 2021 20:09:40

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-13T12:44:01-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd3b4e64a-b76f-4021-b282-225ff2ad2fef'	System	13 Mar 2021 17:44:14
User entered 'No (N)'	System	13 Mar 2021 17:44:14

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-13T12:44:05-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd3b4e64a-b76f-4021-b282-225ff2ad2fef'	System	13 Mar 2021 17:44:14
User entered 'No (N)'	System	13 Mar 2021 17:44:14

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-13T12:44:12-05:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'd3b4e64a-b76f-4021-b282-225ff2ad2fef'	System	13 Mar 2021 17:44:14
User entered '13 Mar 2021 12:44:12'	System	13 Mar 2021 17:44:14

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-22T10:18:13-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ca71e0ce-349d-40bc-a3a4-7547a2b378d7'	System	22 Mar 2021 14:18:23
User entered 'No (N)'	System	22 Mar 2021 14:18:23

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-22T10:18:15-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ca71e0ce-349d-40bc-a3a4-7547a2b378d7'	System	22 Mar 2021 14:18:23
User entered 'No (N)'	System	22 Mar 2021 14:18:23

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-22T10:18:19-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'ca71e0ce-349d-40bc-a3a4-7547a2b378d7'	System	22 Mar 2021 14:18:23
User entered '22 Mar 2021 10:18:19'	System	22 Mar 2021 14:18:23

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-31T08:27:04-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'be15b4b4-94f2-4582-8baf-8a5e6380fe31'	System	31 Mar 2021 12:27:15
User entered 'No (N)'	System	31 Mar 2021 12:27:15

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-31T08:27:07-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'be15b4b4-94f2-4582-8baf-8a5e6380fe31'	System	31 Mar 2021 12:27:15
User entered 'No (N)'	System	31 Mar 2021 12:27:15

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-31T08:27:10-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: 'be15b4b4-94f2-4582-8baf-8a5e6380fe31'	System	31 Mar 2021 12:27:15
User entered '31 Mar 2021 08:27:10'	System	31 Mar 2021 12:27:15

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-04-27T18:07:21-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '70d3a07c-d445-4a8f-b833-517502a00090' User entered 'Yes (Y)'	System	28 Apr 2021 23:07:42
	System	28 Apr 2021 23:07:42

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-04-27T18:07:25-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '70d3a07c-d445-4a8f-b833-517502a00090' User entered 'No (N)'	System	28 Apr 2021 23:07:42
	System	28 Apr 2021 23:07:42

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-04-27T18:07:29-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '70d3a07c-d445-4a8f-b833-517502a00090' User entered 'No (N)'	System	28 Apr 2021 23:07:42
	System	28 Apr 2021 23:07:42

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-04-27T18:07:40-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '70d3a07c-d445-4a8f-b833-517502a00090'	System	28 Apr 2021 23:07:42
User entered 'Yes (Y)'	System	28 Apr 2021 23:07:42

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Please 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-04-27T18:07:46-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '70d3a07c-d445-4a8f-b833-517502a00090'	System	28 Apr 2021 23:07:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Apr 2021 23:07:42

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-04-27T18:07:50-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '70d3a07c-d445-4a8f-b833-517502a00090' User entered '27 Apr 2021 18:07:50'	System	28 Apr 2021 23:07:42
	System	28 Apr 2021 23:07:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-05-01T12:59:46-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '17accabc-da41-4f31-b824-eb343eef1c89'	System	01 May 2021 16:59:57
User entered 'No (N)'	System	01 May 2021 16:59:57

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

Have you been exposed to someone with 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 (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-05-01T12:59:49-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '17accabc-da41-4f31-b824-eb343eef1c89'	System	01 May 2021 16:59:57
User entered 'No (N)'	System	01 May 2021 16:59:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-05-01T12:59:53-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '17accabc-da41-4f31-b824-eb343eef1c89'	System	01 May 2021 16:59:57
User entered '01 May 2021 12:59:53'	System	01 May 2021 16:59:57

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 10:23:18

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 10:23:18

US3412030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:23:18
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 10:23:18

US3412030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:28:51

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)	26 Apr 2021 07:15:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-22T10:18:31-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '87bdd918-2138-47fe-9a53-50af7506e62f' User entered 'No (N)'	System	22 Mar 2021 14:18:39
	System	22 Mar 2021 14:18:39

US3412030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:28:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3BA69BC3-8F61-4900-A16E-88504AF06A83)', Time: '2021-03-22T10:18:36-04:00', User OID: 'PatientReportedOutcome (US3412030)', ODM File OID: '87bdd918-2138-47fe-9a53-50af7506e62f' User entered '22 Mar 2021 10:18:36'	System	22 Mar 2021 14:18:39
	System	22 Mar 2021 14:18:39

US3412030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Oct 2020 15:25:25

US3412030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered '23 Oct 2020'	Mason Urban (b) (4)	23 Oct 2020 15:25:25

US3412030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Oct 2020 15:25:25

US3412030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered empty.	Mason Urban (b) (4)	23 Oct 2020 15:25:25

US3412030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Oct 2020 15:25:38

US3412030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:14:23
User entered 'I'	System	23 Oct 2020 15:25:38

US3412030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:07:41

US3412030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '28 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	01 Dec 2020 16:53:50
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 20:07:41

US3412030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4)	01 Dec 2020 16:54:02
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	25 Nov 2020 20:07:41

US3412030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 14:17:57
User entered 'left voicemail 25 nov 2020 @ 1506.'	(b) (4), (b) (6)	25 Nov 2020 20:07:41

US3412030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	01 Dec 2020 16:59:24

US3412030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'I'	System	01 Dec 2020 16:59:24

US3412030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Dec 2020 17:43:37

US3412030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '23 Dec 2020'	Mason Urban (b) (4)	23 Dec 2020 17:43:37

US3412030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Dec 2020 17:43:37

US3412030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Mason Urban (b) (4)	23 Dec 2020 17:43:37

US3412030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Dec 2020 17:43:46

US3412030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'I'	System	23 Dec 2020 17:43:46

US3412030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Mason Urban (b) (4)	19 Feb 2021 18:28:17

US3412030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 18:28:17

US3412030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 18:28:17

US3412030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'PATIENT NOT CONTACTED DUE TO SITE ERROR. SITE STAFF INSTRUCTED TO COMPLETE SAFETY CALLS ALONGSIDE OPEN LABEL PHASE'	Mason Urban (b) (4)	19 Feb 2021 18:28:17

US3412030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Feb 2021 18:27:55

US3412030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered '1'	System	19 Feb 2021 18:27:55

US3412030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:35:43

US3412030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:35:43

US3412030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 14:35:43

US3412030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'VISIT4'	System	04 Mar 2021 14:35:43

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '04 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '07:52'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered '04 Mar 2021 07:52'	System	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '97.1' F	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '60'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'bpm'	System	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'breaths/min'	System	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '122'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'mmHg'	System	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '80'	Andrea Newlands (b) (4)	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered 'mmHg'	System	29 Mar 2021 20:29:30

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10

US3412030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10

US3412030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Andrea Newlands (b) (4)	04 Mar 2021 14:37:19

US3412030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 14:37:19

US3412030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:37:40

US3412030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:37:40

US3412030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '08:00'	Andrea Newlands (b) (4)	04 Mar 2021 14:37:40

US3412030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered '04 Mar 2021 08:00'	System	04 Mar 2021 14:37:40

US3412030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:37:47

US3412030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:50:10
User entered '1'	System	04 Mar 2021 14:37:47

US3412030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Mar 2021 15:14:32

US3412030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '25 Mar 2021'	Mason Urban (b) (4)	25 Mar 2021 15:14:32

US3412030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Mar 2021 15:14:32

US3412030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Mason Urban (b) (4)	25 Mar 2021 15:14:32

US3412030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Mar 2021 15:14:37

US3412030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:56
User entered 'I'	System	25 Mar 2021 15:14:37

US3412030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:28:45

US3412030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:28:45

US3412030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:28:45

US3412030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:28:45

US3412030

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:28:58

US3412030

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 18:28:58

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:04

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:04

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:04

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 21:42:04

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:42
User entered '0'	Andrea Newlands (b) (4)	07 Apr 2021 20:51:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:50:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:34
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User closed query 'Per IRT, this participant was unblinded under amendment 5; however, the protocol version is recorded here as amendment 6 or later. Please confirm and update the data.' (Site from DM).		20 Apr 2021 09:49:00
Query 'Per IRT, this participant was unblinded under amendment 5; however, the protocol version is recorded here as amendment 6 or later. Please confirm and update the data.' answered with 'Hello Subject was unblinded under amendment 5. however, due to site error subject was not eligible to receive vaccine through work at that point and site made an error unblinding. subject was approved by sponsor and all information was reversed in endpoint to allow subject to receive vaccine through site on 05-Jan-2021. subject did consent at this point to 24-dec-2020 consent at that visit.' (Site from DM).	Steven Anderson (b) (4)	19 Apr 2021 17:25:10
	(b) (4)	
Signature has been broken.	Steven Anderson (b) (4)	19 Apr 2021 17:23:06
	(b) (4)	
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	Steven Anderson (b) (4)	19 Apr 2021 17:23:06
User opened query 'Per IRT, this participant was unblinded under amendment 5; however, the protocol version is recorded here as amendment 6 or later. Please confirm and update the data.' (Site from DM).	(b) (4)	
Query 'Per IRT: This participant was unblinded under amendment 5; however, the protocol version is recorded as amendment 6 or later. Please confirm and update the data.' canceled (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 18:02:47
User opened query 'Per IRT: This participant was unblinded under amendment 5; however, the protocol version is recorded as amendment 6 or later. Please confirm and update the data.' (Site from DM).		17 Apr 2021 18:02:26
User signature succeeded.		17 Apr 2021 18:02:14
	Richard Powell (b) (4)	16 Apr 2021 13:52:42
User closed query 'Per CDM: Per sponsor review, please complete this field.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:03:06

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per sponsor review, please complete this field.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	07 Apr 2021 20:51:55
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4)	07 Apr 2021 20:51:50
User opened query 'Per CDM: Per sponsor review, please complete this field.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:10:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:50:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:42
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 11:58:00
User closed query 'Per IRT, subject was unblinded on 28DEC2020. Please review and reconcile.' (Site from DM).		13 Apr 2021 11:57:56
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Subject was unblinded by error on 28DEC2020. Per sponsor subject was allowed to stay in study and was reconsented under amendment 6 on 05JAN2021' (Site from System).	Andrea Newlands (b) (4)	12 Apr 2021 15:54:35
Query 'Per IRT, subject was unblinded on 28DEC2020. Please review and reconcile.' ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	12 Apr 2021 15:53:38
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	12 Apr 2021 15:46:53
Signature has been broken.	Andrea Newlands (b) (4)	12 Apr 2021 15:46:53
User entered '28 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	12 Apr 2021 15:46:53
User opened query 'Per IRT, subject was unblinded on 28DEC2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:09:20
User closed query 'Per IRT, subject was unblinded on 28DEC2020. Please review and reconcile.' (Site from DM).		12 Apr 2021 15:00:27
Query 'Per IRT, subject was unblinded on 28DEC2020. Please review and reconcile.' ' answered with 'Subject was unblinded by error on 28DEC2020. Per sponsor subject was allowed to stay in study and was unblinded correctly on 05JAN2021' (Site from DM).		09 Apr 2021 12:52:21
User opened query 'Per IRT, subject was unblinded on 28DEC2020. Please review and reconcile.' (Site from DM).		08 Apr 2021 13:03:18

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:08:18
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:08:18
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	05 Jan 2021 21:43:08
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Jan 2021 21:42:43

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '1'	System	05 Jan 2021 21:42:43

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:28:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	05 Jan 2021 21:43:08
User entered empty.	System	05 Jan 2021 21:42:43

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '185.2' cm	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '99.8' kg	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '29.09702'	System	05 Jan 2021 21:46:08
DataPoint set to visible.	System	05 Jan 2021 21:43:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '185.2' cm	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '99.8' kg	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '29.09702'	System	05 Jan 2021 21:46:08
DataPoint set to visible.	System	05 Jan 2021 21:43:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14:05'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '5 Jan 2021 14:05'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '36.5' C	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (Oral)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '58'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '16'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '138'	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '88'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '185.2' cm	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '99.8' kg	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '29.09702'	System	05 Jan 2021 21:46:08
DataPoint set to visible.	System	05 Jan 2021 21:43:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14:53'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '5 Jan 2021 14:53'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '36.6' C	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (Oral)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '60'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '15'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '130'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '82'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	05 Jan 2021 21:46:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:28

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:46:28

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Melissa Fuson (b) (4)	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mRNA-1273'	System	05 Jan 2021 21:47:07
DataPoint set to visible.	System	05 Jan 2021 21:43:08

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14:21'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '5 Jan 2021 14:21'	System	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Left Arm (LEFT ARM)'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'ONCE'	System	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 21:47:07

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:26

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:26

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14:11'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:26

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '5 Jan 2021 14:11'	System	05 Jan 2021 21:47:26

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:42

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:51

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:42

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14:12'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:42

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:51

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '5 Jan 2021 14:12'	System	05 Jan 2021 21:47:42

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	05 Jan 2021 21:47:48

US3412030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	05 Jan 2021 21:47:48

US3412030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Jan 2021 15:47:59

US3412030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered '12 Jan 2021'	Mason Urban (b) (4)	12 Jan 2021 15:47:59

US3412030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	12 Jan 2021 15:47:59

US3412030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered empty.	Mason Urban (b) (4)	12 Jan 2021 15:47:59

US3412030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Jan 2021 15:48:05

US3412030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	12 Jan 2021 15:48:05

US3412030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	12 Jan 2021 15:48:05
DataPoint set to visible.	System	12 Jan 2021 15:48:05

US3412030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 21:43:02

US3412030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '2 Feb 2021'	Steven Anderson (b) (4)	02 Feb 2021 21:43:02

US3412030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Home (Home)'	Steven Anderson (b) (4)	02 Feb 2021 21:43:02

US3412030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'OLD29'	System	02 Feb 2021 21:43:02

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '2 Feb 2021'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '10:05'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '2 Feb 2021 10:05'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '97.7' F	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '63'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '16'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '120'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '80'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '2 Feb 2021'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '11:28'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '2 Feb 2021 11:28'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '97.8' F	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '71'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '16'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '125'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '78'	Steven Anderson (b) (4)	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	02 Feb 2021 21:44:14

US3412030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:21

US3412030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '2 Feb 2021'	Steven Anderson (b) (4)	02 Feb 2021 21:44:21

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

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)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mRNA-1273'	System	02 Feb 2021 21:44:39
DataPoint set to visible.	System	12 Jan 2021 15:48:05

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '2 Feb 2021'	Steven Anderson (b) (4)	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '10:57'	Steven Anderson (b) (4)	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '2 Feb 2021 10:57'	System	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'ONCE'	System	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 21:44:39

US3412030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 21:44:44

US3412030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	02 Feb 2021 21:44:44

US3412030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Feb 2021 19:28:22

US3412030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered '9 Feb 2021'	Mason Urban (b) (4)	09 Feb 2021 19:28:22

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Feb 2021 19:28:22

US3412030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered empty.	Mason Urban (b) (4)	09 Feb 2021 19:28:22

US3412030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Feb 2021 19:28:26

US3412030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	09 Feb 2021 19:28:26

US3412030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:14

US3412030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:14

US3412030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:14

US3412030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'OLD57'	System	04 Mar 2021 14:38:14

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '07:52'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '04 Mar 2021 07:52'	System	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '97.1' F	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '60'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '122'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '80'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	04 Mar 2021 14:38:51

US3412030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26

US3412030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Andrea Newlands (b) (4)	04 Mar 2021 14:38:57

US3412030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 14:38:57

US3412030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 14:39:09

US3412030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 14:39:09

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '08:00'	Andrea Newlands (b) (4)	04 Mar 2021 14:39:09

US3412030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '04 Mar 2021 08:00'	System	04 Mar 2021 14:39:09

US3412030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:28:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 166, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:32:16
Query 'Per DM CLR: Per Safety Follow-up Diary Day 166, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'subject was seen by pcp for regular prescription follow up' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 12:54:33
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 166, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 16:03:13
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:00:27

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod sting, LLT: Bee sting - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:19:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 18:19:39
Data point term sent to Coder	System	24 Nov 2020 17:29:03
Coding entries removed.	Melissa Fuson (b) (4)	24 Nov 2020 17:28:28
User entered 'MULTIPLE BEE STINGS GENERALIZED PRIMARILY ON LOWER EXTREMITIES' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Nov 2020 17:28:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod sting, LLT: Bee sting - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 17:07:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 17:07:58
User closed query 'Per DM CLR: Please specify the location of MULIPLE BEE STINGS (e.g., Generalized, Chest, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:54:18
Data point term sent to Coder	System	29 Sep 2020 17:46:55
Query 'Per DM CLR: Please specify the location of MULIPLE BEE STINGS (e.g., Generalized, Chest, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'GENERALIZED BUT PRIMARILY ON LOWER EXTREMITIES ' (Site from DM).	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:46:17
Coding entries removed.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:45:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'MULIPLE BEE STINGS GENERALIZED PRIMARILY ON LOWER EXTREMITIES' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:45:52
User opened query 'Per DM CLR: Please specify the location of MULIPLE BEE STINGS (e.g., Generalized, Chest, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:17:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod sting, LLT: Bee sting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:22:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:22:23
Data point term sent to Coder	System	11 Aug 2020 20:03:48
User entered 'muliple bee stings'	(b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:36:58
Query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' answered with 'resolved. ' (Site from DM).	Jacob sekinger (b) (4)	15 Sep 2020 13:43:35
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 13:43:11
User opened query 'Per CDM, a response Yes/No is required for this field. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 06:05:45
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:19:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:45:44
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	27 Aug 2020 12:31:32
User entered '02 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	11 Aug 2020 20:05:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:05:03
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Aug 2020 20:03:42
User entered '00:00'	(b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User entered empty.	System	11 Aug 2020 20:05:03
User entered '02 Aug 2020 00:00'	System	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '05 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	11 Aug 2020 20:05:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:05:03
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	11 Aug 2020 20:03:42
User entered '00:00'	(b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User entered empty.	System	11 Aug 2020 20:05:03
User entered '05 Aug 2020 00:00'	System	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

US3412030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:07:26
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'confirm and updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:33:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:33:40
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:52:06
User entered 'Not Applicable (NOT APPLICABLE)'		11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 03:41:59
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'UPDATED TO NOT RELATED' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 17:28:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 17:28:28
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:07:22
User entered 'Not Applicable (NOT APPLICABLE)'		11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Per CDM: AE started after First Dose, however 'Action taken with IP' is 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 03:42:40
Query 'Per CDM: AE started after First Dose, however 'Action taken with IP' is 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'UPDATED TO NONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 17:28:51
User entered 'None (NONE)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 17:28:28
User opened query 'Per CDM: AE started after First Dose, however 'Action taken with IP' is 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:08:06
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:05:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 20:05:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 20:05:20
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 20:03:42
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 09:56:56
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'TYLENOL ' (Site from DM).	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:12
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:18:34
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[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 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 20:03:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
Amendment Manager: User entered '0'	System	21 Aug 2020 01:20:02
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:19:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
Amendment Manager: User entered '0'	System	21 Aug 2020 01:20:02
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:19:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:36
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:19:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 11:18:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 11:18:37
Data point term sent to Coder	System	15 Sep 2020 14:07:52
User entered 'Brief intermittent dizziness'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:38:32
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Sep 2020 14:07:38
User entered '07 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User entered empty.	System	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '07 Aug 2020'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User entered empty.	System	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'None (NONE)'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	15 Sep 2020 14:13:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Jacob sekinger (b) (4)	15 Sep 2020 14:13:26
User entered '0'	(b) (4)	
	System	15 Sep 2020 14:07:38
	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Sep 2020 14:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 14:13:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jacob sekinger (b) (4)	15 Sep 2020 14:13:26
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 14:07:38
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[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 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Jacob sekinger (b) (4)	15 Sep 2020 14:07:38

US3412030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User entered '0'	System	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40
User entered '0'	System	15 Sep 2020 14:07:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 06:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 06:06:52
Data point term sent to Coder	System	01 Mar 2021 16:12:06
User entered 'worsening back pain/muscle spasm'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '14 Sep 2020'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User entered empty.	System	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '15 Sep 2020'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User entered empty.	System	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'No (N)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4) Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

US3412030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'None (NONE)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'I'	(b) (4) Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered '0'	(b) (4) Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[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 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	Andrea Newlands (b) (4)	01 Mar 2021 16:11:21

US3412030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:47
User entered empty.	(b) (4)	01 Mar 2021 16:11:21
	Andrea Newlands (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User entered '0'	System	01 Mar 2021 16:11:21

US3412030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43
User entered 'I'	System	01 Mar 2021 16:11:21

US3412030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:28:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 19:49:30
User entered	System	27 Apr 2021 19:48:49
'USA-US061-2021-mRNA-1273-P301000019'		
User entered 'New'	(b) (4), (b) (6)	27 Apr 2021 19:48:49

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 05:06:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 05:06:28
Data point term sent to Coder	System	27 Apr 2021 18:40:48
User entered 'Worsening BPH/urinary retention'	(b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '18 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '1'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '18 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '1'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Site was notified of SAE during safety call completed on 27 APR 2021. Patient presented to the ED on 18 APR 2021 for urinary retention. Patient was hospitalized until 22 APR 2021 following patient's TURP procedure. SAE has resolved.'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 18:39:56

US3412030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:28:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 18:39:56

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:28:51

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
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) (4), (b) (6)	14 Oct 2020 04:27:43
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 'CONTACTED PARTICIPANT HEADACHED REPORTED BY ACCIDENT' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Oct 2020 16:53:31
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)	05 Oct 2020 11:27:11
User closed query 'Per CDM, subject reported medication to treat pain or fever on Diary Dose 1 Temperature form, however Prior/Concomitant Medication page is not completed for fever/pain. Please complete page or provide explanation.' (Site from DM).		15 Sep 2020 14:31:30

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:28:51

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM, subject reported medication to treat Jacob sekinger pain or fever on Diary Dose 1 Temperature form, however Prior/Concomitant Medication page is not completed for fever/pain. Please complete page or provide explanation.' answered with 'fever/pain was due to bee stings patient received while golfing on 08/03/2020' (Site from DM).	(b) (4)	15 Sep 2020 14:23:34
User opened query 'Per CDM, subject reported medication to treat pain or fever on Diary Dose 1 Temperature form, however Prior/Concomitant Medication page is not completed for fever/pain. Please complete page or provide explanation.' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 14:04:56
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	20 Aug 2020 16:50:52
		05 Aug 2020 18:07:02

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 16:53:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:53:17
Data point term sent to Coder	System	20 Aug 2020 16:52:34
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:51:47

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'HTN'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:51:47

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '20'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:19:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:51:47
User entered 'UN UNK 1990'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:51:47

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:51:47
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:51:47

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:51:47

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:51:47

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 16:53:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:53:19
Data point term sent to Coder	System	20 Aug 2020 16:52:35
User entered 'OMEPRAZOLE'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:52:33

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'GERD'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '40'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:52:33

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:19:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:52:33
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:52:33

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:52:33
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:52:33

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:52:33

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:52:33

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 16:55:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:55:17
Data point term sent to Coder	System	20 Aug 2020 16:54:37
User entered 'FAMOTIDINE'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:54:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'GERD'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '40'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:54:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:19:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:54:05
User entered 'UN May 2020'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:54:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:54:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:54:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:54:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:54:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 16:56:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 16:56:22
Data point term sent to Coder	System	20 Aug 2020 16:55:43
User entered 'TAMSULOSIN'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:55:12

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'BPH'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '.4'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:55:12

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:19:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 16:55:12
User entered 'UN UNK 2017'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:55:12

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 16:55:12
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:55:12

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 16:55:12

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 16:55:12

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:52:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:52:36
Data point term sent to Coder	System	29 Sep 2020 17:52:14
User entered 'ACETAMINOPHEN'	Mylene Asmar-Rios	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	(b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'MULTIPLE BEE STINGS GENERALIZED BUT PRIMAIRLY ON LEGS'	(b) (4)	
	Mylene Asmar-Rios	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data	(b) (4)	
required.	Mylene Asmar-Rios	29 Sep 2020 17:47:46
	(b) (4)	
DataPoint inactivated with code reason code Data not	Mylene Asmar-Rios	20 Aug 2020 16:56:00
required.	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '500'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'mg (mg)'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'once (ONCE)'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (ORAL)'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '03 Aug 2020'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '0'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	(b) (4) Mylene Asmar-Rios	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '03 Aug 2020'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	(b) (4)	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	20 Aug 2020 16:56:00

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User entered empty.	System	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mylene Asmar-Rios	20 Aug 2020 16:56:00
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User entered empty.	System	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mylene Asmar-Rios	20 Aug 2020 16:56:00
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:04
User entered empty.	System	29 Sep 2020 17:51:14
DataPoint activated with code reason code Data required.	Mylene Asmar-Rios	29 Sep 2020 17:47:46
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Aug 2020 16:56:00
	Mylene Asmar-Rios	
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MUSCLE SPASM / BACK PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:27:02
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MUSCLE SPASM / BACK PAIN should be recorded, and update con med indication or provide clarification. ' answered with 'NOTHING IN SOURCE ABOUT CONDITIONING WORSENING' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	12 Jan 2021 15:24:49
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MUSCLE SPASM / BACK PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:31:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:36:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:36:22
Data point term sent to Coder	System	05 Nov 2020 14:28:51
User entered 'CYCLOBENZAPRINE'	Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 14:26:10

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

Name of Medication

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not Jacob sekinger required.	(b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'MUSCLE SPASM / BACK PAIN'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '10'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'mg (mg)'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'three times daily (TID)'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '14 Sep 2020'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '0'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '15 Sep 2020'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User entered '3'	System	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User entered '1'	System	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:13:51
User entered '804 (804)'	System	05 Nov 2020 14:28:05
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	05 Nov 2020 14:26:10
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	15 Sep 2020 14:16:25

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 14:38:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:38:19
Data point term sent to Coder	System	05 Nov 2020 14:29:52
User entered 'IBUPROFEN'	Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'BACK PAIN / MUSCLE SPASM'	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '400' reason for change: Data Entry Error	Melissa Fuson (b) (4)	12 Jan 2021 15:27:12
	(b) (4)	
User entered '200'	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'twice daily (BID)'	(b) (4) Melissa Fuson (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'UN UNK 1990'	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	05 Nov 2020 14:29:03
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 14:29:03

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of PLANTAR FASCIITIS worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:11:19
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of PLANTAR FASCIITIS worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'not due to worsening' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 17:59:07
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of PLANTAR FASCIITIS worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:24:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:50:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:50:51
Data point term sent to Coder	System	08 Dec 2020 18:50:04
User entered 'DICLOFENAC'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'PLANTAR FASCIITIS'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '75'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'mg (mg)'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'as needed (PRN)'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '28 Nov 2020'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	05 Jan 2021 21:48:45
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '30 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	05 Jan 2021 21:48:45
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	Melissa Fuson (b) (4)	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User entered empty.	System	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User entered empty.	System	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:14:13
User entered empty.	System	08 Dec 2020 18:49:29

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 22:42:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 22:42:31
Data point term sent to Coder	System	05 Jan 2021 21:51:10
User entered 'VOLTAREN'	Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 21:51:25
User entered 'No (N)' reason for change: Data Entry Error	System	05 Jan 2021 21:51:25
User opened query 'Data is required. Please complete.' (Site from System).	Melissa Fuson (b) (4)	05 Jan 2021 21:51:25
User entered empty.	(b) (4)	
	System	05 Jan 2021 21:51:05
	Melissa Fuson (b) (4)	05 Jan 2021 21:51:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'PLANTAR FASCIITIS'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered '75' reason for change: Data Entry Error	Melissa Fuson (b) (4)	12 Jan 2021 15:26:29
	(b) (4)	
User entered '175'	Melissa Fuson (b) (4)	05 Jan 2021 21:51:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'as needed (PRN)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	05 Jan 2021 21:51:05
	(b) (4)	

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Oral (ORAL)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '01 Dec 2020'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered '0'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 21:51:05

US3412030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:28:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 18:40:42
User entered 'Yes (Y)' reason for change: New Information		27 Apr 2021 18:40:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:08:44
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 18:07:08

US3412030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:41:02

US3412030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'TURP procedure'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:41:02

US3412030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:41:02

US3412030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:41:02

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'USA-US061-2021-MRNA-1273-P301000019'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Yes (Y)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Yes (Y)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Richard'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Powell'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'OH'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'US'	(b) (4) System	27 Apr 2021 19:53:05

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:53:05

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'USA-US061-2021-MRNA-1273-P301000019'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Yes (Y)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Yes (Y)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'No (N)'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Richard'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'Powell'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 19:51:31
User entered 'OH'	System	27 Apr 2021 19:48:49

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered 'US'	(b) (4) System	27 Apr 2021 19:53:05

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:53:05

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '27/Apr/2021 12:53'	(b) (4) System	27 Apr 2021 19:53:05

US3412030

Folder: SAE USA-US061-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:51

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.	Richard Powell (b) (4)	28 Apr 2021 21:46:19
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 19:53:05
User entered '0'		27 Apr 2021 19:52:18