

US3412153 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

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US3412153

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Participant ID

US3412153

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

US3412153

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 AUG 2020

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

Folder OID SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	_____
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Date of Informed Consent (*dd MMM yyyy*) 06 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version
Amendment 1
Amendment 2
Amendment 3
Amendment 4
Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail
Withdrew Consent
Inclusion/Exclusion
Cohort Full
Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3412153

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

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 04:51:50

Generated On: 09 Jun 2021 17:37:32

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Condition	ALLERGIC RHINITIS (PERENNIAL TO MOLD DUST)
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
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 04:51:50

Generated On: 09 Jun 2021 17:37:32

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
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 04:51:50

Generated On: 09 Jun 2021 17:37:32

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
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 04:51:50

Generated On: 09 Jun 2021 17:37:32

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Condition	DEMEROL ALLERGY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:29 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 09:29
Height (<i>xxx.x</i>)	173 cm
Weight (<i>xxx.x</i>)	148.7 kg
BMI (<i>xxx.x</i>)	49.68425 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 04:51:50

Generated On: 09 Jun 2021 17:37:32

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

6 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Date of assessment (*dd MMM yyyy*) 6 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 6 AUG 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

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 04:51:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 142989

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 02:39:59

Generated On: 09 Jun 2021 17:37:32

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 02:39:59

Generated On: 09 Jun 2021 17:37:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:29 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 09:29
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 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 02:39:59

Generated On: 09 Jun 2021 17:37:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:17 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:17
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	100 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 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) _____

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 10:45

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 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	6 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:14 (24 HR)
Collection date and time (derived)	6 AUG 2020 10:14

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Collection date (<i>dd MMM yyyy</i>)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:18	6 AUG 2020 10:18
Nasopharyngeal Swab 2	No		

US3412153

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 97.5 °F

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

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

PC Time Stamp 06 AUG 2020 11:26

PC Open Date & Time 06 AUG 2020 11:05

PC Close Date & Time 06 AUG 2020 13:35

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 06 AUG 2020 20:58
PC Open Date & Time 06 AUG 2020 14:30
PC Close Date & Time 07 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

PC Time Stamp	07 AUG 2020 22:07
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

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

PC Time Stamp	08 AUG 2020 21:06
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 09 AUG 2020 22:38

PC Open Date & Time 09 AUG 2020 12:00

PC Close Date & Time 10 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

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

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

PC Time Stamp	10 AUG 2020 21:50
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

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

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

PC Time Stamp	11 AUG 2020 21:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 05:43
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

06 AUG 2020 11:28

PC Open Date & Time

06 AUG 2020 11:05

PC Close Date & Time

06 AUG 2020 13:35

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

06 AUG 2020 20:59

PC Open Date & Time

06 AUG 2020 14:30

PC Close Date & Time

07 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	07 AUG 2020 22:07
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 3

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 AUG 2020 21:06

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 AUG 2020 22:38

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 5

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	10 AUG 2020 21:50
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 21:37

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 AUG 2020 05:43

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

No

Yes

PC Time stamp	06 AUG 2020 11:30
PC Open Date & Time	06 AUG 2020 11:05
PC Close Date & Time	06 AUG 2020 13:35

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

No

Yes

PC Time stamp	06 AUG 2020 21:00
PC Open Date & Time	06 AUG 2020 14:30
PC Close Date & Time	07 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 22:08
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	08 AUG 2020 21:07
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 22:39
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 21:51
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

Yes

PC Time stamp	11 AUG 2020 21:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

Yes

PC Time stamp	13 AUG 2020 05:44
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp 13 AUG 2020 21:20

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp 15 AUG 2020 00:09

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 21:20
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 AUG 2020 00:11
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3412153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:08 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 15:08
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

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)	03 SEP 2020
Time of assessment (00:00-23:59)	16:34 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 16:34
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was the pregnancy test performed? Yes
No

Date of test (dd MMM yyyy) 03 SEP 2020

Test performed Urine
Serum

Result Positive
Negative

Was FSH sample collected? Yes
No

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

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 16:01 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 16:01

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

US3412153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 03 SEP 2020

Collection time (*00:00-23:59*) 15:21 (24 HR)

Collection date and time (derived) 03 SEP 2020 15:21

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Collection date (<i>dd MMM yyyy</i>)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:24	03 SEP 2020 15:24
Nasopharyngeal Swab 2	No		

US3412153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 97.4 °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 03 SEP 2020 16:36

PC Open Date & Time 03 SEP 2020 16:21

PC Close Date & Time 03 SEP 2020 18:51

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp 04 SEP 2020 00:07
PC Open Date & Time 03 SEP 2020 19:46
PC Close Date & Time 04 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 SEP 2020 12:44
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 00:12
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

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** 97.7 °F

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

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

PC Time Stamp 06 SEP 2020 19:11

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 21:12
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp 09 SEP 2020 09:37

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

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

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

PC Time Stamp	09 SEP 2020 20:45
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

03 SEP 2020 16:37

PC Open Date & Time

03 SEP 2020 16:21

PC Close Date & Time

03 SEP 2020 18:51

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

04 SEP 2020 00:08

PC Open Date & Time

03 SEP 2020 19:46

PC Close Date & Time

04 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 2

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	04 SEP 2020 12:45
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 3

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

Please select one response below

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

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

- Yes
- No

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

30

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

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

- Yes
- No

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

30

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

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

Please select one response below

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

PC Time Stamp

06 SEP 2020 00:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 4

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

Please select one response below

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

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

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

PC Time Stamp	06 SEP 2020 19:12
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 21:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 07:55

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

09 SEP 2020 20:45

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

No

Yes

PC Time stamp	03 SEP 2020 16:39
PC Open Date & Time	03 SEP 2020 16:21
PC Close Date & Time	03 SEP 2020 18:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

No

Yes

PC Time stamp	04 SEP 2020 00:08
PC Open Date & Time	03 SEP 2020 19:46
PC Close Date & Time	04 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 12:46
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 19:13
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 21:12
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 07:56
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 20:46
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

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	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

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	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3412153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:50

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:39:58

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 OCT 2020

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

Folder OID VISIT3

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:45 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 15:45
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

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.

US3412153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Was the sample collected? Yes No

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

Collection time (*00:00-23:59*) 15:53 (24 HR)

Collection date and time (derived) 08 OCT 2020 15:53

US3412153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:39:59

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 08 OCT 2020 21:49:50

Patient Cloud Open Date & Time 06 OCT 2020 00:01

Patient Cloud Close Date & Time 10 OCT 2020 23:59

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 15 OCT 2020 11:26:37

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

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

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 20 OCT 2020 00:01:39

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

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

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission

05 NOV 2020 16:50:23

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Yes

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

No

Yes

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

Date and time of submission 10 NOV 2020 08:48:55

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

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

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 07:54:59
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 110

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

No

Yes

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

No

Yes

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

Date and time of submission 24 NOV 2020 08:03:52

Patient Cloud Open Date & Time 21 NOV 2020 00:01

Patient Cloud Close Date & Time 25 NOV 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 117

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

No

Yes

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

No

Yes

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

Date and time of submission 01 DEC 2020 09:00:55

Patient Cloud Open Date & Time 28 NOV 2020 00:01

Patient Cloud Close Date & Time 02 DEC 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 08:09:12
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 03:05:56
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 15:18:51
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 17:05:16
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 10:28:02
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 00:31:46
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 18 JAN 2021 12:09:04

Patient Cloud Open Date & Time 16 JAN 2021 00:01

Patient Cloud Close Date & Time 20 JAN 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 23 JAN 2021 08:46:05

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 30 JAN 2021 11:19:45

Patient Cloud Open Date & Time 30 JAN 2021 00:01

Patient Cloud Close Date & Time 03 FEB 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 01:14:31
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Yes

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

No

Yes

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

Date and time of submission 14 FEB 2021 12:49:26

Patient Cloud Open Date & Time 13 FEB 2021 00:01

Patient Cloud Close Date & Time 17 FEB 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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	20 FEB 2021 08:30:27
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 28 FEB 2021 16:57:58

Patient Cloud Open Date & Time 27 FEB 2021 00:01

Patient Cloud Close Date & Time 03 MAR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 00:01:27
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 00:01:32
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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	21 MAR 2021 18:48:21
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 03 APR 2021 01:52:34

Patient Cloud Open Date & Time 03 APR 2021 00:01

Patient Cloud Close Date & Time 07 APR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 10:01:16
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 11:13:32
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 00:10:54
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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	03 MAY 2021 16:00:27
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	08 MAY 2021 00:01
Patient Cloud Close Date & Time	12 MAY 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	29 MAY 2021 00:01
Patient Cloud Close Date & Time	02 JUN 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	08 SEP 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 02 OCT 2021 00:01

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#) 10 NOV 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 DEC 2021 00:01

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 09 FEB 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 600

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 30 MAR 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2022 00:01
Patient Cloud Close Date & Time	04 MAY 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2022 00:01
Patient Cloud Close Date & Time	03 AUG 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 740

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 AUG 2022 00:01

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 747

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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°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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3412153

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:37:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 16:58:19

US3412153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:33:25

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:33:25

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:26:44

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:44

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 MAR 2021

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

Folder OID VISIT4

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

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) _____

US3412153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

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.

US3412153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 02 MAR 2021

Collection time (*00:00-23:59*) 12:37 (24 HR)

Collection date and time (derived) 02 MAR 2021 12:37

US3412153

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3412153

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:27:12

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412153

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

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 _____

US3412153

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3412153

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:37:32

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"/>

US3412153

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:37:32

Generate Next COVID-19 Assessment

Yes

No

US3412153

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 MAR 2021

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

Folder OID UNBLND_DECIDE

US3412153

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Date of updated informed consent (*dd MMM yyyy*) 13 JAN 2021

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

Was the participant unblinded? Yes
No

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

Date of unblinding (*dd MMM yyyy*) 02 MAR 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3412153

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 MAR 2021

Collection time (*00:00-23:59*) 12:37 (24 HR)

Collection date and time (derived) 02 MAR 2021 12:37

US3412153

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:26:43

Generated On: 09 Jun 2021 17:37:32

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 MAR 2021

Collection time (*00:00 - 23:59*) 12:40

Collection Date and Time (derived) 02 MAR 2021 12:40

US3412153

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:32:41

Generated On: 09 Jun 2021 17:37:32

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 05:37:30

Generated On: 09 Jun 2021 17:37:32

AEID

Adverse event

CHRONIC HYPERTENSION
WORSENING

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)

24 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)

10 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

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EAB) (1725)

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US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 05:37:30

Generated On: 09 Jun 2021 17:37:32

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)	

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 05:37:30

Generated On: 09 Jun 2021 17:37:32

AEID	
Adverse event	WORSENING CHRONIC HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 05:37:30

Generated On: 09 Jun 2021 17:37:32

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 05:37:30

Generated On: 09 Jun 2021 17:37:32

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	12 AUG 2020
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)	13 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 05:37:30

Generated On: 09 Jun 2021 17:37:32

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

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:36:28

Generated On: 09 Jun 2021 17:37:32

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

Yes

No

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

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Name of Medication LISINOPRIL-HYDROCHLOROTHIAZIDE

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 12.5/20

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify	
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Name of Medication VENTOLIN MDI

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 190

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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US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2012

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Name of Medication HYZAAR/HYDROCHOLOROTHY
AZIDE

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 50/12.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

	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) 24 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes
No

Indication INFLUENZA PREOPHYLAXIS

Dose per administration 0.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 07 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 07 JAN 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Name of Medication CARVEDILOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 6.25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

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*) 30 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Name of Medication FUROSEMIDE

Prophylaxis Yes
No

Indication HYPERTENSION

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

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) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

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*) 30 MAR 2021

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

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) 16 Apr 2021 13:30:56

Generated On: 09 Jun 2021 17:37:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 MAR 2021	ECHOCARDIOGRAM	Diagnostic	
30 MAR 2021	CARDIAC ANGIOGRAM	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:37:32

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

- AE (specify)
- SAE (specify)
- Death
- Lost To Follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation (specify)
- Study Terminated By Sponsor
- Withdrawal of consent by participant (specify)
- Due to SARS-COV-2
- Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:32

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

Audit

US3412153 (Prod: New Horizons Clinical Research)

US3412153

Form: Participant Creation

Generated On: 09 Jun 2021 17:37:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:38:36
User entered 'US3412153'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:43

US3412153

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:45:57
User entered 'Yes (Y)'		06 Aug 2020 14:37:12

US3412153

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:45:57
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:44

US3412153

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:45:57
User entered 'Clinic (Clinic)'		06 Aug 2020 14:37:12

US3412153

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'SCRN'	System	06 Aug 2020 14:37:12

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:45

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '46'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'YEARS'	System	06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '46'	System	06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered 'Female (F)'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '1'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered empty.		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:22
User entered '0'		06 Aug 2020 14:37:55

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered '06 Aug 2020'		06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'Aug 2020'	System	06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '2020'	System	06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered 'Amendment 1 (1)'		06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered empty.		06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered empty.		06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered 'No (N)'		06 Aug 2020 14:38:53

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:46:43
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 13:44:44

US3412153

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '1'	System	06 Aug 2020 14:39:05

US3412153

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:46:55
User entered 'Yes (Y)'	(b) (4)	06 Aug 2020 14:39:05

US3412153

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:37:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:47:20
User entered 'Yes (Y)'		18 Aug 2020 17:33:56

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:01:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 05:11:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 05:11:40
Data point term sent to Coder	System	11 Nov 2020 13:47:34
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	11 Nov 2020 13:47:16
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	11 Nov 2020 13:47:16
User entered 'ALLERGIC RHINITIS (PERENNIAL TO MOLD DUST)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Nov 2020 13:47:16
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:48:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:34
Data point term sent to Coder	System	18 Aug 2020 17:37:47
User entered 'ALLERGIC RHINITIS'	(b) (4), (b) (6)	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'UN UNK 2012'	(b) (4), (b) (6)	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'Yes (Y)'		18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'		18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'Jan 2012'	System	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '2012'	System	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:37:13

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:34
Data point term sent to Coder	System	18 Aug 2020 17:37:49
User entered 'ASTHMA'	(b) (4), (b) (6)	18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'UN UNK 2012'		18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'		18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'Yes (Y)'		18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'		18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'Jan 2012'	System	18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '2012'	System	18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:37:29

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
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) (b) (4)	18 Aug 2020 18:22:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:33
Data point term sent to Coder	System	18 Aug 2020 17:37:49
User entered 'HYPERTENSION'	(b) (4), (b) (6)	18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'UN UNK 2005'		18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'		18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'Yes (Y)'		18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'		18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'Jan 2005'	System	18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '2005'	System	18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:37:43

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 18:22:36
Data point term sent to Coder	System	18 Aug 2020 17:38:53
User entered 'ANXIETY'	(b) (4), (b) (6)	18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'UN UNK 2018'		18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'		18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'Yes (Y)'		18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered empty.		18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'Jan 2018'	System	18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '2018'	System	18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:38:36

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 15:51:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 15:51:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:48:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 18:22:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 18:22:35
Data point term sent to Coder	System	18 Aug 2020 17:38:51
User entered 'DEMEROL ALLERGY'	(b) (4), (b) (6)	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered empty.		18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '1'		18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:48:09
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:38:50

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered 'Yes (Y)'		18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered '6 Aug 2020'		18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered '09:29'		18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '6 Aug 2020 09:29'	System	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered '173' cm	(b) (4)	18 Aug 2020 17:35:31
DataPoint set to visible.	System	06 Aug 2020 14:39:05

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered '148.7' kg	(b) (4)	18 Aug 2020 17:35:31
DataPoint set to visible.	System	06 Aug 2020 14:39:05

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
Amendment Manager: User entered '49.68425'	System	16 Sep 2020 23:45:09
User entered '49.7'	System	18 Aug 2020 17:35:31
DataPoint set to visible.	System	06 Aug 2020 14:39:05

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'kg/m2'	System	18 Aug 2020 17:35:31
DataPoint set to visible.	System	06 Aug 2020 14:39:05

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User closed query 'Data is required. Please provide.' (Site from System).		19 Aug 2020 12:46:45
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).		18 Aug 2020 17:35:52
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 17:35:31
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered empty.		18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'bpm'	System	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'breaths/min'	System	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'mmHg'	System	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:48:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'mmHg'	System	18 Aug 2020 17:35:31

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34

US3412153

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34

US3412153

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:49:07
User entered 'Yes (Y)'		18 Aug 2020 17:39:02

US3412153

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
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 08:59:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		03 Sep 2020 20:05:38
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:49:07
User entered '6 Aug 2020'		18 Aug 2020 17:39:02

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered '6 Aug 2020'		18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered 'Yes (Y)'	(b) (4)	18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered empty.		18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered '0'		18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered empty.		18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:37:32

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:50:51
User entered '0'		18 Aug 2020 17:39:34

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered 'Yes (Y)'		18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered '6 Aug 2020'		18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered 'Urine (URINE)'		18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered 'No (N)'		18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
User closed query 'Please enter date of pregnancy test' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:51:50
Query 'Please enter date of pregnancy test' answered with 'FSH not collected' (Site from CRA).	Jacob sekinger (b) (4)	22 Sep 2020 18:47:00
User opened query 'Please enter date of pregnancy test' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 18:52:04
DataPoint Un-verified.	(b) (4), (b) (6)	25 Aug 2020 18:51:31
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
User closed query 'Collection time noted in source as 09:55 - please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:51:58
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:51:54
Query 'Collection time noted in source as 09:55 - please confirm and update accordingly' answered with 'FSH not collected' (Site from CRA).	Jacob sekinger (b) (4)	22 Sep 2020 18:47:11
User opened query 'Collection time noted in source as 09:55 - please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 18:53:25
DataPoint Un-verified.	(b) (4), (b) (6)	25 Aug 2020 18:51:36
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:51:03
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	18 Aug 2020 17:40:03

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'Yes (Y)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered 'No (N)'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered empty.		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered '0'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered '0'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered '1'	(b) (4), (b) (6)	18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered '0'		18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 17:40:55

US3412153

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:53:35
User entered empty.		18 Aug 2020 17:40:55

US3412153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:54:14
User entered 'Yes (Y)'		06 Aug 2020 14:39:49

US3412153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:54:14
User entered '06 Aug 2020'		06 Aug 2020 14:39:49

US3412153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:54:14
User entered 'Clinic (Clinic)'		06 Aug 2020 14:39:49

US3412153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'VISIT1'	System	06 Aug 2020 14:39:49

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:55:42
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 14:24:58

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:55:42
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:27:53
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:27:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 14:24:58
User entered '142989' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 14:24:58

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:55:42
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 14:24:58

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

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)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:40
DataPoint Un-verified.		25 Aug 2020 18:55:56
DataPoint Verified.		25 Aug 2020 18:55:42
User entered 'Yes (Y)'		18 Aug 2020 17:41:33

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

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)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:55:42
User entered 'No (N)'		18 Aug 2020 17:41:33

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:55:42
User entered 'Yes (Y)'	(b) (4)	18 Aug 2020 17:41:33

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:55:42
User entered 'No (N)'		18 Aug 2020 17:41:33

US3412153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:55:42
User entered 'No (N)'		18 Aug 2020 17:41:33

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered missing code ND - Not Done.		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered 'Yes (Y)'	(b) (4)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '6 Aug 2020'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '09:29'	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '6 Aug 2020 09:29'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '37.0' C		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered 'Oral (Oral)'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered empty.		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '90'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'bpm'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '18'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'breaths/min'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '128'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '88'	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered missing code ND - Not Done.		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered 'Yes (Y)'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '6 Aug 2020'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
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)	19 Aug 2020 12:46:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 17:43:37
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).	(b) (4), (b) (6)	18 Aug 2020 17:43:29
User entered '11:17'	(b) (4), (b) (6)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '6 Aug 2020 11:17'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '97.5' F		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered 'Oral (Oral)'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered empty.		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '80'	(b) (4)	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'bpm'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '16'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'breaths/min'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '132'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:00:45
User entered '100'		18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	18 Aug 2020 17:43:29

US3412153

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:02:53
User entered 'No (N)'		18 Aug 2020 17:43:45

US3412153

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:02:53
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:43:45

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:03:01
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 17:43:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 17:43:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 17:43:59
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 17:43:53
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:01
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:03:01
User entered empty.		18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:01
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:18:49
User closed query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4)	23 Mar 2021 05:47:27
Query 'Per CDM: Please provide a response for Was FSH sample collected?' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	22 Mar 2021 12:55:07
DataPoint Un-verified.	(b) (4)	22 Mar 2021 12:55:03
Signature has been broken.	Andrea Newlands (b) (4)	22 Mar 2021 12:55:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 12:55:03
User opened query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:07:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:01
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:01
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:03:01
User entered empty.		18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered empty.	System	18 Aug 2020 17:43:53

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:47
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:47
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:03:47
User entered '06 Aug 2020'		06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:03:47
User entered '10:45'		06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '06 Aug 2020 10:45'	System	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:03:47
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
DataPoint Verified.		25 Aug 2020 19:03:47
User entered 'ONCE'	System	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 14:50:31

US3412153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:04
User entered 'Yes (Y)'		18 Aug 2020 17:44:34

US3412153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:04
User entered '6 Aug 2020'		18 Aug 2020 17:44:34

US3412153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:55:04
User entered '10:14'		18 Aug 2020 17:44:34

US3412153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '6 Aug 2020 10:14'	System	18 Aug 2020 17:44:34

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:37:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:04:37
User entered '6 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:04:37
User entered 'Yes (Y)'		18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:04:37
User entered '10:18'		18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '6 Aug 2020 10:18'	System	18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:04:37
User entered 'No (N)'		18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:04:37
User entered empty.		18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered empty.	System	18 Aug 2020 17:44:51

US3412153

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:06:01
User entered 'Yes (Y)'		18 Aug 2020 17:44:54

US3412153

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	18 Aug 2020 17:44:54

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:26:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0aa9373e-28d0-4bb1-b17b-30dde89c944e'	System	06 Aug 2020 15:26:48
User entered 'Yes (Y)'	System	06 Aug 2020 15:26:48

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:26:21', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0aa9373e-28d0-4bb1-b17b-30dde89c944e'	System	06 Aug 2020 15:26:48
User entered '97.5'	System	06 Aug 2020 15:26:48

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:26:27', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0aa9373e-28d0-4bb1-b17b-30dde89c944e'	System	06 Aug 2020 15:26:48
User entered 'No (N)'	System	06 Aug 2020 15:26:48

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:26:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0aa9373e-28d0-4bb1-b17b-30dde89c944e'	System	06 Aug 2020 15:26:48
User entered '06 Aug 2020 11:26'	System	06 Aug 2020 15:26:48

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 11:05'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 13:35'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:58:19', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1618168b-00ea-417d-a705-d7263a2f5735'	System	07 Aug 2020 00:58:42
User entered 'Yes (Y)'	System	07 Aug 2020 00:58:42

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:58:24', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1618168b-00ea-417d-a705-d7263a2f5735'	System	07 Aug 2020 00:58:42
User entered '98.6'	System	07 Aug 2020 00:58:42

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:58:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1618168b-00ea-417d-a705-d7263a2f5735'	System	07 Aug 2020 00:58:42
User entered 'No (N)'	System	07 Aug 2020 00:58:42

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:58:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1618168b-00ea-417d-a705-d7263a2f5735'	System	07 Aug 2020 00:58:42
User entered '06 Aug 2020 20:58'	System	07 Aug 2020 00:58:42

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 14:30'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 2'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:06:48', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8541c711-de12-40a6-9cc2-d8372a026c8b'	System	08 Aug 2020 02:07:28
User entered 'Yes (Y)'	System	08 Aug 2020 02:07:28

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8541c711-de12-40a6-9cc2-d8372a026c8b'	System	08 Aug 2020 02:07:28
User entered '98.5'	System	08 Aug 2020 02:07:28

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:18', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8541c711-de12-40a6-9cc2-d8372a026c8b'	System	08 Aug 2020 02:07:28
User entered 'No (N)'	System	08 Aug 2020 02:07:28

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8541c711-de12-40a6-9cc2-d8372a026c8b'	System	08 Aug 2020 02:07:28
User entered '07 Aug 2020 22:07'	System	08 Aug 2020 02:07:28

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 3'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:15', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e6e620b5-3fda-4bc5-8f70-3a846f76d0fa'	System	09 Aug 2020 01:06:27
User entered 'Yes (Y)'	System	09 Aug 2020 01:06:27

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:20', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e6e620b5-3fda-4bc5-8f70-3a846f76d0fa'	System	09 Aug 2020 01:06:27
User entered '98.7'	System	09 Aug 2020 01:06:27

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e6e620b5-3fda-4bc5-8f70-3a846f76d0fa'	System	09 Aug 2020 01:06:27
User entered 'No (N)'	System	09 Aug 2020 01:06:27

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e6e620b5-3fda-4bc5-8f70-3a846f76d0fa'	System	09 Aug 2020 01:06:27
User entered '08 Aug 2020 21:06'	System	09 Aug 2020 01:06:27

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 4'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:37:40', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1b09fc9d-ecb8-47e3-adea-aca5fc9479ca'	System	10 Aug 2020 02:38:15
User entered 'Yes (Y)'	System	10 Aug 2020 02:38:15

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1b09fc9d-ecb8-47e3-adea-aca5fc9479ca'	System	10 Aug 2020 02:38:15
User entered '98.2'	System	10 Aug 2020 02:38:15

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1b09fc9d-ecb8-47e3-adea-aca5fc9479ca'	System	10 Aug 2020 02:38:15
User entered 'No (N)'	System	10 Aug 2020 02:38:15

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1b09fc9d-ecb8-47e3-adea-aca5fc9479ca'	System	10 Aug 2020 02:38:15
User entered '09 Aug 2020 22:38'	System	10 Aug 2020 02:38:15

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 5'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:32', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3fbc3f5c-611e-47a8-8b79-c036313695f6'	System	11 Aug 2020 01:50:45
User entered 'Yes (Y)'	System	11 Aug 2020 01:50:45

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3fbc3f5c-611e-47a8-8b79-c036313695f6'	System	11 Aug 2020 01:50:45
User entered '98.1'	System	11 Aug 2020 01:50:45

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3fbc3f5c-611e-47a8-8b79-c036313695f6'	System	11 Aug 2020 01:50:45
User entered 'No (N)'	System	11 Aug 2020 01:50:45

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3fbc3f5c-611e-47a8-8b79-c036313695f6'	System	11 Aug 2020 01:50:45
User entered '10 Aug 2020 21:50'	System	11 Aug 2020 01:50:45

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 6'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bec28359-4fea-421b-9257-da7f633fbfc6'	System	12 Aug 2020 01:37:18
User entered 'Yes (Y)'	System	12 Aug 2020 01:37:18

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bec28359-4fea-421b-9257-da7f633fbfc6'	System	12 Aug 2020 01:37:18
User entered '98.7'	System	12 Aug 2020 01:37:18

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bec28359-4fea-421b-9257-da7f633fbfc6'	System	12 Aug 2020 01:37:18
User entered 'No (N)'	System	12 Aug 2020 01:37:18

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:17', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bec28359-4fea-421b-9257-da7f633fbfc6'	System	12 Aug 2020 01:37:18
User entered '11 Aug 2020 21:37'	System	12 Aug 2020 01:37:18

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 7'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:42:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '621e4fc0-e8ce-4a4c-8759-86ad3b62a404'	System	13 Aug 2020 09:43:26
User entered 'Yes (Y)'	System	13 Aug 2020 09:43:26

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '621e4fc0-e8ce-4a4c-8759-86ad3b62a404'	System	13 Aug 2020 09:43:26
User entered '98.6'	System	13 Aug 2020 09:43:26

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:09', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '621e4fc0-e8ce-4a4c-8759-86ad3b62a404'	System	13 Aug 2020 09:43:26
User entered 'No (N)'	System	13 Aug 2020 09:43:26

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '621e4fc0-e8ce-4a4c-8759-86ad3b62a404'	System	13 Aug 2020 09:43:26
User entered '13 Aug 2020 05:43'	System	13 Aug 2020 09:43:26

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:27:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bc335a1d-9646-43cd-9b71-96462a89445e'	System	06 Aug 2020 15:28:03
User entered 'None (1)'	System	06 Aug 2020 15:28:03

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:27:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bc335a1d-9646-43cd-9b71-96462a89445e'	System	06 Aug 2020 15:28:03
User entered 'No (N)'	System	06 Aug 2020 15:28:03

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:27:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bc335a1d-9646-43cd-9b71-96462a89445e'	System	06 Aug 2020 15:28:03
User entered 'No (N)'	System	06 Aug 2020 15:28:03

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:27:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bc335a1d-9646-43cd-9b71-96462a89445e'	System	06 Aug 2020 15:28:03
User entered 'None (1)'	System	06 Aug 2020 15:28:03

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:28:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bc335a1d-9646-43cd-9b71-96462a89445e'	System	06 Aug 2020 15:28:03
User entered '06 Aug 2020 11:28'	System	06 Aug 2020 15:28:03

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 11:05'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 13:35'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:58:54', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1edf09e-f469-40a8-b9e9-14a03570b039'	System	07 Aug 2020 00:59:26
User entered 'None (1)'	System	07 Aug 2020 00:59:26

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:58:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1edf09e-f469-40a8-b9e9-14a03570b039'	System	07 Aug 2020 00:59:26
User entered 'No (N)'	System	07 Aug 2020 00:59:26

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1edf09e-f469-40a8-b9e9-14a03570b039'	System	07 Aug 2020 00:59:26
User entered 'No (N)'	System	07 Aug 2020 00:59:26

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:19', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1edf09e-f469-40a8-b9e9-14a03570b039'	System	07 Aug 2020 00:59:26
User entered 'None (1)'	System	07 Aug 2020 00:59:26

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1edf09e-f469-40a8-b9e9-14a03570b039'	System	07 Aug 2020 00:59:26
User entered '06 Aug 2020 20:59'	System	07 Aug 2020 00:59:26

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 14:30'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 2'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bb9db509-6d5d-4527-87d5-249834662096'	System	08 Aug 2020 02:07:59
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 02:07:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:46', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bb9db509-6d5d-4527-87d5-249834662096'	System	08 Aug 2020 02:07:59
User entered 'No (N)'	System	08 Aug 2020 02:07:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bb9db509-6d5d-4527-87d5-249834662096'	System	08 Aug 2020 02:07:59
User entered 'No (N)'	System	08 Aug 2020 02:07:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bb9db509-6d5d-4527-87d5-249834662096'	System	08 Aug 2020 02:07:59
User entered 'None (1)'	System	08 Aug 2020 02:07:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:07:57', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bb9db509-6d5d-4527-87d5-249834662096'	System	08 Aug 2020 02:07:59
User entered '07 Aug 2020 22:07'	System	08 Aug 2020 02:07:59

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 3'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bdfbe42c-6860-4ef0-8c51-4421404ac694'	System	09 Aug 2020 01:06:47
User entered 'None (1)'	System	09 Aug 2020 01:06:47

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bdfbe42c-6860-4ef0-8c51-4421404ac694'	System	09 Aug 2020 01:06:47
User entered 'No (N)'	System	09 Aug 2020 01:06:47

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bdfbe42c-6860-4ef0-8c51-4421404ac694'	System	09 Aug 2020 01:06:47
User entered 'No (N)'	System	09 Aug 2020 01:06:47

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:42', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bdfbe42c-6860-4ef0-8c51-4421404ac694'	System	09 Aug 2020 01:06:47
User entered 'None (1)'	System	09 Aug 2020 01:06:47

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:44', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'bdfbe42c-6860-4ef0-8c51-4421404ac694'	System	09 Aug 2020 01:06:47
User entered '08 Aug 2020 21:06'	System	09 Aug 2020 01:06:47

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 4'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'Odd344b4-517a-48a9-b063-3bec038f5222'	System	10 Aug 2020 02:38:52
User entered 'None (1)'	System	10 Aug 2020 02:38:52

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:27', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'odd344b4-517a-48a9-b063-3bec038f5222'	System	10 Aug 2020 02:38:52
User entered 'No (N)'	System	10 Aug 2020 02:38:52

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'odd344b4-517a-48a9-b063-3bec038f5222'	System	10 Aug 2020 02:38:52
User entered 'No (N)'	System	10 Aug 2020 02:38:52

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'odd344b4-517a-48a9-b063-3bec038f5222'	System	10 Aug 2020 02:38:52
User entered 'None (1)'	System	10 Aug 2020 02:38:52

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'odd344b4-517a-48a9-b063-3bec038f5222'	System	10 Aug 2020 02:38:52
User entered '09 Aug 2020 22:38'	System	10 Aug 2020 02:38:52

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 5'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:45', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'cac89d19-e815-4dcc-b71d-02cd90e997a0'	System	11 Aug 2020 01:51:00
User entered 'None (1)'	System	11 Aug 2020 01:51:00

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:48', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'cac89d19-e815-4dcc-b71d-02cd90e997a0'	System	11 Aug 2020 01:51:00
User entered 'No (N)'	System	11 Aug 2020 01:51:00

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'cac89d19-e815-4dcc-b71d-02cd90e997a0'	System	11 Aug 2020 01:51:00
User entered 'No (N)'	System	11 Aug 2020 01:51:00

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:54', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'cac89d19-e815-4dcc-b71d-02cd90e997a0'	System	11 Aug 2020 01:51:00
User entered 'None (1)'	System	11 Aug 2020 01:51:00

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:50:56', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'cac89d19-e815-4dcc-b71d-02cd90e997a0'	System	11 Aug 2020 01:51:00
User entered '10 Aug 2020 21:50'	System	11 Aug 2020 01:51:00

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 6'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:21', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'eec3f65d-49b0-47d7-a122-7b9b6986496f'	System	12 Aug 2020 01:37:37
User entered 'None (1)'	System	12 Aug 2020 01:37:37

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'eec3f65d-49b0-47d7-a122-7b9b6986496f'	System	12 Aug 2020 01:37:37
User entered 'No (N)'	System	12 Aug 2020 01:37:37

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'eec3f65d-49b0-47d7-a122-7b9b6986496f'	System	12 Aug 2020 01:37:37
User entered 'No (N)'	System	12 Aug 2020 01:37:37

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:28', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'eec3f65d-49b0-47d7-a122-7b9b6986496f'	System	12 Aug 2020 01:37:37
User entered 'None (1)'	System	12 Aug 2020 01:37:37

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:35', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'eec3f65d-49b0-47d7-a122-7b9b6986496f'	System	12 Aug 2020 01:37:37
User entered '11 Aug 2020 21:37'	System	12 Aug 2020 01:37:37

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 7'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:21', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'da464dcc-605d-4527-a629-6744f798086d'	System	13 Aug 2020 09:43:34
User entered 'None (1)'	System	13 Aug 2020 09:43:34

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:24', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'da464dcc-605d-4527-a629-6744f798086d'	System	13 Aug 2020 09:43:34
User entered 'No (N)'	System	13 Aug 2020 09:43:34

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'da464dcc-605d-4527-a629-6744f798086d'	System	13 Aug 2020 09:43:34
User entered 'No (N)'	System	13 Aug 2020 09:43:34

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'da464dcc-605d-4527-a629-6744f798086d'	System	13 Aug 2020 09:43:34
User entered 'None (1)'	System	13 Aug 2020 09:43:34

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'da464dcc-605d-4527-a629-6744f798086d'	System	13 Aug 2020 09:43:34
User entered '13 Aug 2020 05:43'	System	13 Aug 2020 09:43:34

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:28:54', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'None (0)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:29:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'None (0)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:29:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'None (0)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:30:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'None (0)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:30:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'None (0)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:30:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'None (0)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:30:21', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered 'No (N)'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T11:30:25', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55c02abe-6d45-4999-afbd-dee092f22891'	System	06 Aug 2020 15:30:28
User entered '06 Aug 2020 11:30'	System	06 Aug 2020 15:30:28

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 11:05'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 13:35'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:38', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'None (0)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'None (0)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'None (0)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T20:59:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'None (0)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T21:00:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'None (0)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T21:00:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'None (0)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T21:00:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered 'No (N)'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-06T21:00:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a592a14d-ed0f-4c5d-b419-70a788e5cea2'	System	07 Aug 2020 01:00:19
User entered '06 Aug 2020 21:00'	System	07 Aug 2020 01:00:19

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Aug 2020 14:30'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 2'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'None (0)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'None (0)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:08', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'None (0)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'None (0)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'None (0)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:15', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'None (0)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:20', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered 'No (N)'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-07T22:08:22', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '820fcbf6-7c8b-4868-b4df-3501f4b964ad'	System	08 Aug 2020 02:08:27
User entered '07 Aug 2020 22:08'	System	08 Aug 2020 02:08:27

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 3'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'None (0)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'None (0)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:53', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'None (0)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'None (0)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:57', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'None (0)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:06:59', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'None (0)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:07:04', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered 'No (N)'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-08T21:07:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '83e34860-8687-430d-b028-c967dcd489c4'	System	09 Aug 2020 01:07:07
User entered '08 Aug 2020 21:07'	System	09 Aug 2020 01:07:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 4'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:56', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'None (0)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:38:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'None (0)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:39:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'None (0)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:39:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'None (0)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:39:08', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'None (0)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:39:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'None (0)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:39:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered 'No (N)'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-09T22:39:18', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3bd80de0-5a72-46c3-9ac9-073f36c2a7ab'	System	10 Aug 2020 02:39:20
User entered '09 Aug 2020 22:39'	System	10 Aug 2020 02:39:20

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 5'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'None (0)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'None (0)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:07', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'None (0)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'None (0)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'None (0)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:15', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'None (0)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:18', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered 'No (N)'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-10T21:51:20', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '22ac1df6-be8f-4587-8abc-11cd66bd1d3c'	System	11 Aug 2020 01:51:22
User entered '10 Aug 2020 21:51'	System	11 Aug 2020 01:51:22

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 6'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'None (0)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'None (0)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'None (0)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:45', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'None (0)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'None (0)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'None (0)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:53', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered 'No (N)'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-11T21:37:56', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2847da86-87f2-450a-983e-36b6bed34595'	System	12 Aug 2020 01:37:58
User entered '11 Aug 2020 21:37'	System	12 Aug 2020 01:37:58

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 7'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'No interference with activity (1)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:46', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'None (0)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'None (0)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'None (0)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:43:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'None (0)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:44:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'None (0)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:44:03', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered 'No (N)'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T05:44:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a03ea9d7-f714-44d2-9c68-f9b535019312'	System	13 Aug 2020 09:44:07
User entered '13 Aug 2020 05:44'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	13 Aug 2020 09:44:07
User entered 'Day 8'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T21:20:18', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '603d5264-e226-4037-b8f2-85fbb9dc295a'	System	14 Aug 2020 01:20:23
User entered 'No interference with activity (1)'	System	14 Aug 2020 01:20:23

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T21:20:21', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '603d5264-e226-4037-b8f2-85fbb9dc295a'	System	14 Aug 2020 01:20:23
User entered '13 Aug 2020 21:20'	System	14 Aug 2020 01:20:23

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	13 Aug 2020 09:44:07
User entered 'Day 9'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-15T00:09:50', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7ef96339-221f-4e8f-8fe2-83bf1d3ce26f'	System	15 Aug 2020 04:09:53
User entered 'None (0)'	System	15 Aug 2020 04:09:53

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-15T00:09:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7ef96339-221f-4e8f-8fe2-83bf1d3ce26f'	System	15 Aug 2020 04:09:53
User entered '15 Aug 2020 00:09'	System	15 Aug 2020 04:09:53

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	13 Aug 2020 09:44:07
User entered 'Day 8'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T21:20:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '539e2911-7a0a-4494-b143-6fd757d71959'	System	14 Aug 2020 01:20:31
User entered 'No (N)'	System	14 Aug 2020 01:20:31

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-13T21:20:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '539e2911-7a0a-4494-b143-6fd757d71959'	System	14 Aug 2020 01:20:31
User entered '13 Aug 2020 21:20'	System	14 Aug 2020 01:20:31

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	13 Aug 2020 09:44:07
User entered 'Day 9'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-15T00:09:57', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4fbab84d-755d-45cb-a6f6-fc8335fde5ef'	System	15 Aug 2020 04:11:52
User entered 'No (N)'	System	15 Aug 2020 04:11:52

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-08-15T00:11:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4fbab84d-755d-45cb-a6f6-fc8335fde5ef'	System	15 Aug 2020 04:11:52
User entered '15 Aug 2020 00:11'	System	15 Aug 2020 04:11:52

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 09:44:07

US3412153

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 09:44:07

US3412153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:06:42
User entered 'Yes (Y)'		18 Aug 2020 17:46:10

US3412153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 19:06:42
User entered '13 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:46:10

US3412153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:06:42
User entered 'Contact Made (CONTACT MADE)'		18 Aug 2020 17:46:10

US3412153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:06:42
User entered empty.		18 Aug 2020 17:46:10

US3412153

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 19:06:49
User entered 'Yes (Y)'		18 Aug 2020 17:46:13

US3412153

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	18 Aug 2020 17:46:13

US3412153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:12:03
User entered 'Yes (Y)'		27 Aug 2020 21:15:20

US3412153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:12:03
User entered '20 Aug 2020'		27 Aug 2020 21:15:20

US3412153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:12:03
User entered 'Contact Made (CONTACT MADE)'		27 Aug 2020 21:15:20

US3412153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:12:03
User entered empty.		27 Aug 2020 21:15:20

US3412153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:53:52
User entered 'Yes (Y)'		27 Aug 2020 21:15:26

US3412153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'I'	System	27 Aug 2020 21:15:26

US3412153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:13:28
User entered 'Yes (Y)'		27 Aug 2020 21:15:50

US3412153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:13:28
User entered '27 Aug 2020'		27 Aug 2020 21:15:50

US3412153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:13:28
User entered 'Contact Made (CONTACT MADE)'		27 Aug 2020 21:15:50

US3412153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:13:28
User entered empty.		27 Aug 2020 21:15:50

US3412153

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:13:33
User entered 'Yes (Y)'		27 Aug 2020 21:15:57

US3412153

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	27 Aug 2020 21:15:57

US3412153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:33:15
User entered 'Yes (Y)'		03 Sep 2020 20:05:38

US3412153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:33:15
User entered '3 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	22 Sep 2020 19:04:45
User entered '6 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	22 Sep 2020 19:00:52
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:05:38

US3412153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:33:15
User entered 'Clinic (Clinic)'		03 Sep 2020 20:05:38

US3412153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'VISIT2'	System	03 Sep 2020 20:05:38

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:05:09
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:05:09
User entered '03 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:05:09
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:25
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:25
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:25
User entered '03 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:04:25
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:53:39
User entered '06 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:00:40
User closed query 'Per source, time of vitals is 15:08? Please review source confirm and update' (Site from CRA).		23 Oct 2020 16:00:38
Query 'Per source, time of vitals is 15:08? Please review source confirm and update' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:24
User entered '15:08' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:15
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:57
DataPoint Verified.		19 Oct 2020 13:41:22
User opened query 'Per source, time of vitals is 15:08? Please review source confirm and update' (Site from CRA).		19 Oct 2020 13:36:37
User entered '09:29'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '03 Sep 2020 15:08'	System	19 Oct 2020 15:10:15
User entered '03 Sep 2020 09:29'	System	22 Sep 2020 19:05:09
User entered '03 Aug 2020 09:29'	System	22 Sep 2020 19:04:25
User entered '06 Aug 2020 09:29'	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered '37.0' C	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:00:49
User closed query 'Per source, pulse = 70? Please review and update as appropriate' (Site from CRA).	(b) (4)	23 Oct 2020 16:00:46
Query 'Per source, pulse = 70? Please review and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:30
User entered '70' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:15
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:42:03
DataPoint Verified.	(b) (4)	19 Oct 2020 13:41:22
User opened query 'Per source, pulse = 70? Please review and update as appropriate' (Site from CRA).	(b) (4)	19 Oct 2020 13:37:24
User entered '90'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'bpm'	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:00:55
User closed query 'Per source, resp rate = 16? Please review and update as appropriate' (Site from CRA).	(b) (4)	23 Oct 2020 16:00:52
Query 'Per source, resp rate = 16? Please review and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:37
User entered '16' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:15
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:42:05
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:22
User opened query 'Per source, resp rate = 16? Please review and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 13:39:11
User entered '18'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'breaths/min'	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered '128'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered '88'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:05:09
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:05:09
User entered '03 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:05:09
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:25
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:25
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:25
User entered '03 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:04:25
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:58:05
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:58:05
User entered '06 Aug 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:58:05
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:57:49
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
User entered '06 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:46
User closed query 'Per source, temp = 97.4 F, Pulse = 72, rr= 14 and bp = 118/82. Please review source and update as appropriate' (Site from CRA).		23 Oct 2020 16:01:44
User closed query '16:34 per source? Please review source and update as appropriate' (Site from CRA).		23 Oct 2020 16:01:32
Query 'Per source, temp = 97.4 F, Pulse = 72, rr= 14 and bp = 118/82. Please review source and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:12:23
Query '16:34 per source? Please review source and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:11:05
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:10:57
User entered '16:34' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:10:57
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:10:15
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:34
DataPoint Verified.		19 Oct 2020 13:41:22
User opened query 'Per source, temp = 97.4 F, Pulse = 72, rr= 14 and bp = 118/82. Please review source and update as appropriate' (Site from CRA).		19 Oct 2020 13:41:14
User opened query '16:34 per source? Please review source and update as appropriate' (Site from CRA).		19 Oct 2020 13:40:04
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:57:49
User entered '11:17' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '03 Sep 2020 16:34'	System	19 Oct 2020 15:10:57
User entered '03 Sep 2020 11:17'	System	22 Sep 2020 19:05:09
User entered '03 Aug 2020 11:17'	System	22 Sep 2020 19:04:25
User entered '06 Aug 2020 11:17'	System	22 Sep 2020 18:58:05
User entered '06 Sep 2020 11:17'	System	22 Sep 2020 18:57:49
User entered empty.	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:37
User entered '97.4' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:11:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:39
DataPoint Verified.		19 Oct 2020 13:41:22
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:57:49
User entered '97.5' F reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:58:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:58:32
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:58:32
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:41:22
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:49
User entered '72' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:11:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:44
DataPoint Verified.		19 Oct 2020 13:41:22
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:57:49
User entered '80' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'bpm'	System	22 Sep 2020 18:57:49
User entered empty.	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:51
User entered '14' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:11:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:46
DataPoint Verified.		19 Oct 2020 13:41:22
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:57:49
User entered '16' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'breaths/min'	System	22 Sep 2020 18:57:49
User entered empty.	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:54
User entered '118' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:11:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:48
DataPoint Verified.		19 Oct 2020 13:41:22
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:57:49
User entered '132' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	22 Sep 2020 18:57:49
User entered empty.	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:57
User entered '82' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:11:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:41:50
DataPoint Verified.		19 Oct 2020 13:41:22
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:57:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		22 Sep 2020 18:57:49
User entered '100' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:57:49
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 18:53:39
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'mmHg'	System	22 Sep 2020 18:57:49
User entered empty.	System	22 Sep 2020 18:53:39

US3412153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:42:35
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:02:56

US3412153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:42:35
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:56
User entered '03 Sep 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:04:56
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:02:56
User entered '06 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:02:56

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered 'Urine (URINE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered 'Negative (NEGATIVE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:24
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:37:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered empty.	System	22 Sep 2020 19:06:19

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:44:30
User entered 'Yes (Y)'		03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:46:14
User entered empty.		03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:46:14
User entered empty.		03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:46:14
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:04:45
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	22 Sep 2020 19:04:45
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 19:00:52
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:46:14
User entered '16:01'		03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '3 Sep 2020 16:01'	System	03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 15:17:27
DataPoint Verified.		19 Oct 2020 13:46:14
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'due to patient request the opposite arm was injected. PI reviewed and has found no issues with data integrity or subject safety. All injection sites are documented consistently in both unblinded and blinded source' (Site from System).	Steven Anderson (b) (4)	08 Oct 2020 20:33:02
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	03 Sep 2020 20:06:48
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
DataPoint Verified.		19 Oct 2020 13:46:14
User entered 'ONCE'	System	03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 20:06:48

US3412153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:12
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:55

US3412153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:12
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:55

US3412153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:12
User entered '15:21'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:06:55

US3412153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '03 Sep 2020 15:21'	System	22 Sep 2020 19:06:55

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:20
User entered '03 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:20
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:20
User entered '15:24'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '03 Sep 2020 15:24'	System	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:20
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:20
User entered empty.	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered empty.	System	22 Sep 2020 19:07:20

US3412153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:48:25
User entered 'Yes (Y)'		10 Sep 2020 19:57:54

US3412153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	10 Sep 2020 19:57:54

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:36:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3d2dd416-4ed9-4175-8716-6c072c042b97'	System	03 Sep 2020 20:37:02
User entered 'Yes (Y)'	System	03 Sep 2020 20:37:02

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:36:48', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3d2dd416-4ed9-4175-8716-6c072c042b97'	System	03 Sep 2020 20:37:02
User entered '97.4'	System	03 Sep 2020 20:37:02

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:36:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3d2dd416-4ed9-4175-8716-6c072c042b97'	System	03 Sep 2020 20:37:02
User entered 'No (N)'	System	03 Sep 2020 20:37:02

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:36:59', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3d2dd416-4ed9-4175-8716-6c072c042b97'	System	03 Sep 2020 20:37:02
User entered '03 Sep 2020 16:36'	System	03 Sep 2020 20:37:02

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 16:21'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 18:51'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:07:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8365f788-d146-47c8-be21-1343522e715f'	System	04 Sep 2020 04:07:55
User entered 'Yes (Y)'	System	04 Sep 2020 04:07:55

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:07:44', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8365f788-d146-47c8-be21-1343522e715f' User entered '97.9'	System	04 Sep 2020 04:07:55
	System	04 Sep 2020 04:07:55

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:07:48', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8365f788-d146-47c8-be21-1343522e715f'	System	04 Sep 2020 04:07:55
User entered 'No (N)'	System	04 Sep 2020 04:07:55

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:07:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8365f788-d146-47c8-be21-1343522e715f' User entered '04 Sep 2020 00:07'	System	04 Sep 2020 04:07:55
	System	04 Sep 2020 04:07:55

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 19:46'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 2'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:42:54', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1bb448f-d37e-42bb-b55c-7c519f52690c'	System	04 Sep 2020 16:44:48
User entered 'Yes (Y)'	System	04 Sep 2020 16:44:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:44:31', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1bb448f-d37e-42bb-b55c-7c519f52690c'	System	04 Sep 2020 16:44:48
User entered '99.0'	System	04 Sep 2020 16:44:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:44:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1bb448f-d37e-42bb-b55c-7c519f52690c'	System	04 Sep 2020 16:44:48
User entered 'No (N)'	System	04 Sep 2020 16:44:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:44:46', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1bb448f-d37e-42bb-b55c-7c519f52690c'	System	04 Sep 2020 16:44:48
User entered '04 Sep 2020 12:44'	System	04 Sep 2020 16:44:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 3'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:12:42', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8913ada0-6f97-4c2f-abfc-732cce827b22'	System	06 Sep 2020 04:12:59
User entered 'Yes (Y)'	System	06 Sep 2020 04:12:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:12:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8913ada0-6f97-4c2f-abfc-732cce827b22'	System	06 Sep 2020 04:12:59
User entered '98.2'	System	06 Sep 2020 04:12:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:12:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8913ada0-6f97-4c2f-abfc-732cce827b22'	System	06 Sep 2020 04:12:59
User entered 'No (N)'	System	06 Sep 2020 04:12:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:12:53', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8913ada0-6f97-4c2f-abfc-732cce827b22'	System	06 Sep 2020 04:12:59
User entered '06 Sep 2020 00:12'	System	06 Sep 2020 04:12:59

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 4'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:11:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e48765a5-ee23-44f3-83b6-f27ca2944733'	System	06 Sep 2020 23:11:47
User entered 'Yes (Y)'	System	06 Sep 2020 23:11:47

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:11:40', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e48765a5-ee23-44f3-83b6-f27ca2944733'	System	06 Sep 2020 23:11:47
User entered '97.7'	System	06 Sep 2020 23:11:47

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:11:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e48765a5-ee23-44f3-83b6-f27ca2944733'	System	06 Sep 2020 23:11:47
User entered 'No (N)'	System	06 Sep 2020 23:11:47

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:11:45', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e48765a5-ee23-44f3-83b6-f27ca2944733'	System	06 Sep 2020 23:11:47
User entered '06 Sep 2020 19:11'	System	06 Sep 2020 23:11:47

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 5'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:08', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b445242c-28bc-456c-a0f3-131e0c94cc25'	System	08 Sep 2020 01:12:18
User entered 'Yes (Y)'	System	08 Sep 2020 01:12:18

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b445242c-28bc-456c-a0f3-131e0c94cc25'	System	08 Sep 2020 01:12:18
User entered '99.1'	System	08 Sep 2020 01:12:18

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b445242c-28bc-456c-a0f3-131e0c94cc25'	System	08 Sep 2020 01:12:18
User entered 'No (N)'	System	08 Sep 2020 01:12:18

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:16', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b445242c-28bc-456c-a0f3-131e0c94cc25'	System	08 Sep 2020 01:12:18
User entered '07 Sep 2020 21:12'	System	08 Sep 2020 01:12:18

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 6'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T09:37:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e1e8a0d-e23f-47c0-b384-0f018b5c7432'	System	09 Sep 2020 13:37:43
User entered 'Yes (Y)'	System	09 Sep 2020 13:37:43

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T09:37:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e1e8a0d-e23f-47c0-b384-0f018b5c7432'	System	09 Sep 2020 13:37:43
User entered '97.3'	System	09 Sep 2020 13:37:43

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T09:37:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e1e8a0d-e23f-47c0-b384-0f018b5c7432'	System	09 Sep 2020 13:37:43
User entered 'No (N)'	System	09 Sep 2020 13:37:43

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T09:37:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e1e8a0d-e23f-47c0-b384-0f018b5c7432'	System	09 Sep 2020 13:37:43
User entered '09 Sep 2020 09:37'	System	09 Sep 2020 13:37:43

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 7'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4d3d2e06-86f5-4fc6-9a7f-6855f769e536'	System	10 Sep 2020 00:45:25
User entered 'Yes (Y)'	System	10 Sep 2020 00:45:25

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:16', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4d3d2e06-86f5-4fc6-9a7f-6855f769e536'	System	10 Sep 2020 00:45:25
User entered '98.1'	System	10 Sep 2020 00:45:25

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:20', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4d3d2e06-86f5-4fc6-9a7f-6855f769e536'	System	10 Sep 2020 00:45:25
User entered 'No (N)'	System	10 Sep 2020 00:45:25

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:22', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4d3d2e06-86f5-4fc6-9a7f-6855f769e536'	System	10 Sep 2020 00:45:25
User entered '09 Sep 2020 20:45'	System	10 Sep 2020 00:45:25

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:37:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e73e7505-2ff0-48a4-ba78-0c6107ec50db'	System	03 Sep 2020 20:37:33
User entered 'None (1)'	System	03 Sep 2020 20:37:33

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:37:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e73e7505-2ff0-48a4-ba78-0c6107ec50db'	System	03 Sep 2020 20:37:33
User entered 'No (N)'	System	03 Sep 2020 20:37:33

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:37:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e73e7505-2ff0-48a4-ba78-0c6107ec50db'	System	03 Sep 2020 20:37:33
User entered 'No (N)'	System	03 Sep 2020 20:37:33

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:37:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e73e7505-2ff0-48a4-ba78-0c6107ec50db'	System	03 Sep 2020 20:37:33
User entered 'None (1)'	System	03 Sep 2020 20:37:33

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:37:30', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e73e7505-2ff0-48a4-ba78-0c6107ec50db'	System	03 Sep 2020 20:37:33
User entered '03 Sep 2020 16:37'	System	03 Sep 2020 20:37:33

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 16:21'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 18:51'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:07:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '13b377a3-b947-4a21-ae55-d7a28a7be16c'	System	04 Sep 2020 04:08:11
User entered 'None (1)'	System	04 Sep 2020 04:08:11

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:07:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '13b377a3-b947-4a21-ae55-d7a28a7be16c'	System	04 Sep 2020 04:08:11
User entered 'No (N)'	System	04 Sep 2020 04:08:11

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '13b377a3-b947-4a21-ae55-d7a28a7be16c'	System	04 Sep 2020 04:08:11
User entered 'No (N)'	System	04 Sep 2020 04:08:11

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '13b377a3-b947-4a21-ae55-d7a28a7be16c'	System	04 Sep 2020 04:08:11
User entered 'None (1)'	System	04 Sep 2020 04:08:11

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '13b377a3-b947-4a21-ae55-d7a28a7be16c'	System	04 Sep 2020 04:08:11
User entered '04 Sep 2020 00:08'	System	04 Sep 2020 04:08:11

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 19:46'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 2'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1ba6fb8f-60f5-4e6e-a624-88b5e6243414'	System	04 Sep 2020 16:45:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 16:45:35

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1ba6fb8f-60f5-4e6e-a624-88b5e6243414'	System	04 Sep 2020 16:45:35
User entered 'No (N)'	System	04 Sep 2020 16:45:35

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1ba6fb8f-60f5-4e6e-a624-88b5e6243414'	System	04 Sep 2020 16:45:35
User entered 'No (N)'	System	04 Sep 2020 16:45:35

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:27', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1ba6fb8f-60f5-4e6e-a624-88b5e6243414'	System	04 Sep 2020 16:45:35
User entered 'None (1)'	System	04 Sep 2020 16:45:35

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1ba6fb8f-60f5-4e6e-a624-88b5e6243414'	System	04 Sep 2020 16:45:35
User entered '04 Sep 2020 12:45'	System	04 Sep 2020 16:45:35

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 3'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:13:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:13:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered 'Yes (Y)'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered '30'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered 'Yes (Y)'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered '30'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:48', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered 'None (1)'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4dd3446b-0a47-4ab7-a5a5-818cc76ae82a'	System	06 Sep 2020 04:16:55
User entered '06 Sep 2020 00:16'	System	06 Sep 2020 04:16:55

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 4'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:11:50', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8cb3f4d6-11c5-432d-8195-6dcddb7e7422'	System	06 Sep 2020 23:12:42
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:12:42

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:04', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8cb3f4d6-11c5-432d-8195-6dcddb7e7422'	System	06 Sep 2020 23:12:42
User entered 'No (N)'	System	06 Sep 2020 23:12:42

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:30', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8cb3f4d6-11c5-432d-8195-6dcddb7e7422'	System	06 Sep 2020 23:12:42
User entered 'No (N)'	System	06 Sep 2020 23:12:42

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:37', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8cb3f4d6-11c5-432d-8195-6dcddb7e7422'	System	06 Sep 2020 23:12:42
User entered 'None (1)'	System	06 Sep 2020 23:12:42

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:40', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8cb3f4d6-11c5-432d-8195-6dcddb7e7422'	System	06 Sep 2020 23:12:42
User entered '06 Sep 2020 19:12'	System	06 Sep 2020 23:12:42

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 5'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:21', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '61e70624-b26a-439e-b0d8-c92d387bdcfa'	System	08 Sep 2020 01:12:34
User entered 'None (1)'	System	08 Sep 2020 01:12:34

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:24', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '61e70624-b26a-439e-b0d8-c92d387bdcfa'	System	08 Sep 2020 01:12:34
User entered 'No (N)'	System	08 Sep 2020 01:12:34

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '61e70624-b26a-439e-b0d8-c92d387bdcfa'	System	08 Sep 2020 01:12:34
User entered 'No (N)'	System	08 Sep 2020 01:12:34

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:28', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '61e70624-b26a-439e-b0d8-c92d387bdcfa'	System	08 Sep 2020 01:12:34
User entered 'None (1)'	System	08 Sep 2020 01:12:34

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:30', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '61e70624-b26a-439e-b0d8-c92d387bdcfa'	System	08 Sep 2020 01:12:34
User entered '07 Sep 2020 21:12'	System	08 Sep 2020 01:12:34

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 6'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'fcfe3c44-9042-47df-b4ca-54d3492790c2'	System	09 Sep 2020 11:55:41
User entered 'None (1)'	System	09 Sep 2020 11:55:41

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:28', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'fcfe3c44-9042-47df-b4ca-54d3492790c2'	System	09 Sep 2020 11:55:41
User entered 'No (N)'	System	09 Sep 2020 11:55:41

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:31', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'fcfe3c44-9042-47df-b4ca-54d3492790c2'	System	09 Sep 2020 11:55:41
User entered 'No (N)'	System	09 Sep 2020 11:55:41

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:34', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'fcfe3c44-9042-47df-b4ca-54d3492790c2'	System	09 Sep 2020 11:55:41
User entered 'None (1)'	System	09 Sep 2020 11:55:41

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:37', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'fcfe3c44-9042-47df-b4ca-54d3492790c2'	System	09 Sep 2020 11:55:41
User entered '09 Sep 2020 07:55'	System	09 Sep 2020 11:55:41

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 7'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:27', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7c88f967-f703-43a5-a0f7-9ebb8b2024bc'	System	10 Sep 2020 00:45:39
User entered 'None (1)'	System	10 Sep 2020 00:45:39

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7c88f967-f703-43a5-a0f7-9ebb8b2024bc'	System	10 Sep 2020 00:45:39
User entered 'No (N)'	System	10 Sep 2020 00:45:39

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:31', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7c88f967-f703-43a5-a0f7-9ebb8b2024bc'	System	10 Sep 2020 00:45:39
User entered 'No (N)'	System	10 Sep 2020 00:45:39

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7c88f967-f703-43a5-a0f7-9ebb8b2024bc'	System	10 Sep 2020 00:45:39
User entered 'None (1)'	System	10 Sep 2020 00:45:39

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:35', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7c88f967-f703-43a5-a0f7-9ebb8b2024bc'	System	10 Sep 2020 00:45:39
User entered '09 Sep 2020 20:45'	System	10 Sep 2020 00:45:39

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:38:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'None (0)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:38:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'None (0)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:38:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'None (0)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:38:56', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'None (0)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:38:59', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'None (0)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:39:03', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'None (0)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:39:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered 'No (N)'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-03T16:39:17', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '70317830-1b4f-478f-a0fd-47c6c8906586'	System	03 Sep 2020 20:39:20
User entered '03 Sep 2020 16:39'	System	03 Sep 2020 20:39:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 16:21'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 18:51'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'None (0)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:12', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'None (0)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:14', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'None (0)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:16', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'None (0)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:17', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'None (0)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:19', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'None (0)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered 'No (N)'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T00:08:28', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd8daaa63-cd99-433e-9f83-f6b9f9547649'	System	04 Sep 2020 04:08:34
User entered '04 Sep 2020 00:08'	System	04 Sep 2020 04:08:34

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '03 Sep 2020 19:46'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 2'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:38', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'None (0)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:44', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'Significant; prevents daily activity (3)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:45:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'Significant; prevents daily activity (3)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:46:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'None (0)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:46:04', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'None (0)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:46:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'None (0)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:46:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered 'No (N)'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-04T12:46:20', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '8fec9d78-36c7-4e11-add3-efd90dd2b529'	System	04 Sep 2020 16:46:23
User entered '04 Sep 2020 12:46'	System	04 Sep 2020 16:46:23

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 3'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'No interference with activity (1)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:16:59', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'Some interference with activity (2)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:17:03', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'Some interference with activity (2)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:17:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'None (0)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:17:07', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'None (0)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:17:09', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'None (0)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:17:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered 'No (N)'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T00:17:16', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'f3691ce7-8e96-41a9-ab0a-0513ed850f33'	System	06 Sep 2020 04:17:18
User entered '06 Sep 2020 00:17'	System	06 Sep 2020 04:17:18

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 4'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:44', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'None (0)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'None (0)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:50', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'None (0)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:54', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'None (0)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:56', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'None (0)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:12:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'None (0)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:13:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered 'No (N)'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-06T19:13:03', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '62a0f78a-5c96-4d00-8be2-2182a0638f5a'	System	06 Sep 2020 23:13:08
User entered '06 Sep 2020 19:13'	System	06 Sep 2020 23:13:08

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 5'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:34', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'None (0)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'None (0)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:37', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'None (0)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'None (0)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'None (0)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:42', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'None (0)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:45', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered 'No (N)'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-07T21:12:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '24d0907d-7fb9-4cd2-89ff-d6f324bfac70'	System	08 Sep 2020 01:12:51
User entered '07 Sep 2020 21:12'	System	08 Sep 2020 01:12:51

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 6'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'None (0)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'None (0)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'No interference with activity (1)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:53', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'None (0)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'None (0)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:57', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'None (0)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:55:59', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered 'No (N)'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T07:56:01', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6bddca33-ba3d-4c32-a8cf-c6d882266a3b'	System	09 Sep 2020 11:56:03
User entered '09 Sep 2020 07:56'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	03 Sep 2020 20:06:48
User entered 'Day 7'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'None (0)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:45:40', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'None (0)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:46:06', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:46:09', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'None (0)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:46:11', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'None (0)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:46:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'None (0)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:46:15', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered 'No (N)'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-09-09T20:46:17', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '55eec00f-2c58-45ec-80b5-63a243840ca1'	System	10 Sep 2020 00:46:20
User entered '09 Sep 2020 20:46'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 20:06:48

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	09 Sep 2020 11:56:03
User entered 'Day 8'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:32

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	10 Sep 2020 00:46:20
User entered 'Day 9'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:37:32

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	09 Sep 2020 11:56:03
User entered 'Day 8'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 11:56:03

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	10 Sep 2020 00:46:20
User entered 'Day 9'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

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 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:46:20

US3412153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:37:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:46:20

US3412153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:54:12
User entered 'Yes (Y)'		10 Sep 2020 19:58:07

US3412153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:54:12
User entered '10 Sep 2020'		10 Sep 2020 19:58:07

US3412153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:54:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 19:58:07

US3412153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:54:12
User entered empty.		10 Sep 2020 19:58:07

US3412153

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:54:15
User entered 'Yes (Y)'		10 Sep 2020 19:58:12

US3412153

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	10 Sep 2020 19:58:12

US3412153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:56:38
User entered 'Yes (Y)'		17 Sep 2020 15:34:26

US3412153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:56:38
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:34:26

US3412153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:56:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 15:34:26

US3412153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:56:38
User entered empty.		17 Sep 2020 15:34:26

US3412153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 13:56:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:34:31

US3412153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	17 Sep 2020 15:34:31

US3412153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:58:39
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	24 Sep 2020 18:14:41

US3412153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:58:39
User entered '24 Sep 2020'	Mason Urban (b) (4) (b) (4)	24 Sep 2020 18:14:41

US3412153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:58:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	24 Sep 2020 18:14:41

US3412153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:58:39
User entered empty.	Mason Urban (b) (4) (b) (4)	24 Sep 2020 18:14:41

US3412153

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:58:42
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	24 Sep 2020 18:16:35

US3412153

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	24 Sep 2020 18:16:35

US3412153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:02:12
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:11

US3412153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:02:12
User entered '08 Oct 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:11

US3412153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:02:12
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:11

US3412153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User entered 'VISIT3'	System	08 Oct 2020 20:02:11

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered '08 Oct 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered '15:45'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User entered '08 Oct 2020 15:45'	System	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered '36.8' C	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered '84'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User entered 'bpm'	System	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:41:07
User closed query 'RR = 15 per source? Please confirm and update as appropriate' (Site from CRA).	(b) (4)	23 Oct 2020 15:41:05
Query 'RR = 15 per source? Please confirm and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:13:28
User entered '15' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 15:13:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 14:03:46
DataPoint Verified.	(b) (4)	19 Oct 2020 14:03:42
User opened query 'RR = 15 per source? Please confirm and update as appropriate' (Site from CRA).	(b) (4)	19 Oct 2020 14:03:04
User entered '25'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User entered 'breaths/min'	System	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:56:49
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Oct 2020 14:05:13
User entered '138' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	20 Oct 2020 14:05:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered '136'	Steven Anderson (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User entered 'mmHg'	System	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:03:42
User entered '98'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49
User entered 'mmHg'	System	08 Oct 2020 20:02:58

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49

US3412153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:49

US3412153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:56:23
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Oct 2020 14:05:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	20 Oct 2020 14:05:48
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 14:03:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 20:03:13

US3412153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:56:23
DataPoint Un-verified.	Melissa Fuson (b) (4)	20 Oct 2020 14:05:48
User entered empty; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	20 Oct 2020 14:05:48
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 14:03:59
User entered '08 Oct 2020'	Steven Anderson (b) (4)	08 Oct 2020 20:03:13

US3412153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:05:49
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:03:33

US3412153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:05:49
User entered '08 Oct 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:03:33

US3412153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:05:49
User entered '15:53'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:03:33

US3412153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '08 Oct 2020 15:53'	System	08 Oct 2020 20:03:33

US3412153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:05:44
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:03:39

US3412153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered '1'	System	08 Oct 2020 20:03:39

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 64'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-08T21:49:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1e1f5ea-42b6-4d38-b32c-416e6a7cbeab'	System	09 Oct 2020 01:49:54
User entered 'No (N)'	System	09 Oct 2020 01:49:54

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-08T21:49:46', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1e1f5ea-42b6-4d38-b32c-416e6a7cbeab'	System	09 Oct 2020 01:49:54
User entered 'No (N)'	System	09 Oct 2020 01:49:54

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-08T21:49:50', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e1e1f5ea-42b6-4d38-b32c-416e6a7cbeab' User entered '08 Oct 2020 21:49:50'	System	09 Oct 2020 01:49:54
	System	09 Oct 2020 01:49:54

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 71'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-15T11:26:28', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '25031316-10e7-4c5b-b6c8-7e812bb54bcc'	System	15 Oct 2020 15:26:43
User entered 'No (N)'	System	15 Oct 2020 15:26:43

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-15T11:26:34', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '25031316-10e7-4c5b-b6c8-7e812bb54bcc'	System	15 Oct 2020 15:26:43
User entered 'No (N)'	System	15 Oct 2020 15:26:43

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-15T11:26:37', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '25031316-10e7-4c5b-b6c8-7e812bb54bcc'	System	15 Oct 2020 15:26:43
User entered '15 Oct 2020 11:26:37'	System	15 Oct 2020 15:26:43

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 78'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-20T00:01:33', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '08088d91-4bca-4829-aa58-c88210268182'	System	20 Oct 2020 04:01:45
User entered 'No (N)'	System	20 Oct 2020 04:01:45

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-20T00:01:36', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '08088d91-4bca-4829-aa58-c88210268182'	System	20 Oct 2020 04:01:45
User entered 'No (N)'	System	20 Oct 2020 04:01:45

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-10-20T00:01:39', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '08088d91-4bca-4829-aa58-c88210268182'	System	20 Oct 2020 04:01:45
User entered '20 Oct 2020 00:01:39'	System	20 Oct 2020 04:01:45

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 92'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-05T16:50:16', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1c3140cb-669c-4ec0-9478-b0e41156f9be'	System	05 Nov 2020 21:50:26
User entered 'No (N)'	System	05 Nov 2020 21:50:26

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-05T16:50:20', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1c3140cb-669c-4ec0-9478-b0e41156f9be'	System	05 Nov 2020 21:50:26
User entered 'No (N)'	System	05 Nov 2020 21:50:26

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-05T16:50:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1c3140cb-669c-4ec0-9478-b0e41156f9be'	System	05 Nov 2020 21:50:26
User entered '05 Nov 2020 16:50:23'	System	05 Nov 2020 21:50:26

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 99'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-10T08:48:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2ef4a85d-6516-4662-bb1e-d5d12a30cc9e'	System	10 Nov 2020 13:48:56
User entered 'No (N)'	System	10 Nov 2020 13:48:56

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-10T08:48:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2ef4a85d-6516-4662-bb1e-d5d12a30cc9e'	System	10 Nov 2020 13:48:56
User entered 'No (N)'	System	10 Nov 2020 13:48:56

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-10T08:48:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2ef4a85d-6516-4662-bb1e-d5d12a30cc9e'	System	10 Nov 2020 13:48:56
User entered '10 Nov 2020 08:48:55'	System	10 Nov 2020 13:48:56

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered 'Day 106'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-17T07:54:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7fd5262b-08cb-42d9-8fb2-045d1607697b'	System	17 Nov 2020 12:55:04
User entered 'No (N)'	System	17 Nov 2020 12:55:04

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-17T07:54:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7fd5262b-08cb-42d9-8fb2-045d1607697b'	System	17 Nov 2020 12:55:04
User entered 'No (N)'	System	17 Nov 2020 12:55:04

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-17T07:54:59', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7fd5262b-08cb-42d9-8fb2-045d1607697b'	System	17 Nov 2020 12:55:04
User entered '17 Nov 2020 07:54:59'	System	17 Nov 2020 12:55:04

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 14:50:31

US3412153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:24:01
Data entry locked.	System	06 Aug 2020 14:50:31
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 14:50:31

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2020-11-24T08:03:45', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '67c23d4e-1f31-4e06-b295-4b5f364c3561'	System	24 Nov 2020 13:03:54
User entered 'No (N)'	System	24 Nov 2020 13:03:54

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2020-11-24T08:03:48', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '67c23d4e-1f31-4e06-b295-4b5f364c3561'	System	24 Nov 2020 13:03:54
User entered 'No (N)'	System	24 Nov 2020 13:03:54

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-11-24T08:03:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '67c23d4e-1f31-4e06-b295-4b5f364c3561'	System	24 Nov 2020 13:03:54
User entered '24 Nov 2020 08:03:52'	System	24 Nov 2020 13:03:54

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2020-12-01T09:00:50', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'c9d7a6d7-5219-43f9-963c-ab8520f7e2ac'	System	01 Dec 2020 14:00:59
User entered 'No (N)'	System	01 Dec 2020 14:00:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2020-12-01T09:00:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'c9d7a6d7-5219-43f9-963c-ab8520f7e2ac'	System	01 Dec 2020 14:00:59
User entered 'No (N)'	System	01 Dec 2020 14:00:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-12-01T09:00:55', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'c9d7a6d7-5219-43f9-963c-ab8520f7e2ac'	System	01 Dec 2020 14:00:59
User entered '01 Dec 2020 09:00:55'	System	01 Dec 2020 14:00:59

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2020-12-08T08:09:07', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4811ea7f-bc09-4ff4-bd0d-4ec7488ebe81'	System	08 Dec 2020 13:09:16
User entered 'No (N)'	System	08 Dec 2020 13:09:16

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2020-12-08T08:09:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4811ea7f-bc09-4ff4-bd0d-4ec7488ebe81'	System	08 Dec 2020 13:09:16
User entered 'No (N)'	System	08 Dec 2020 13:09:16

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-12-08T08:09:12', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '4811ea7f-bc09-4ff4-bd0d-4ec7488ebe81'	System	08 Dec 2020 13:09:16
User entered '08 Dec 2020 08:09:12'	System	08 Dec 2020 13:09:16

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2020-12-12T03:05:52', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '901715f7-de49-4187-8801-1dc668118676'	System	12 Dec 2020 08:06:02
User entered 'No (N)'	System	12 Dec 2020 08:06:02

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2020-12-12T03:05:54', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '901715f7-de49-4187-8801-1dc668118676'	System	12 Dec 2020 08:06:02
User entered 'No (N)'	System	12 Dec 2020 08:06:02

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-12-12T03:05:56', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '901715f7-de49-4187-8801-1dc668118676'	System	12 Dec 2020 08:06:02
User entered '12 Dec 2020 03:05:56'	System	12 Dec 2020 08:06:02

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2020-12-20T15:18:47', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '388b6ee9-6091-4296-8201-5ac8940d78d1'	System	20 Dec 2020 20:18:54
User entered 'No (N)'	System	20 Dec 2020 20:18:54

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2020-12-20T15:18:49', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '388b6ee9-6091-4296-8201-5ac8940d78d1'	System	20 Dec 2020 20:18:54
User entered 'No (N)'	System	20 Dec 2020 20:18:54

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-12-20T15:18:51', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '388b6ee9-6091-4296-8201-5ac8940d78d1'	System	20 Dec 2020 20:18:54
User entered '20 Dec 2020 15:18:51'	System	20 Dec 2020 20:18:54

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2020-12-26T17:05:10', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b31cebc3-f815-4a84-b950-f26d4d79beff'	System	26 Dec 2020 22:05:20
User entered 'No (N)'	System	26 Dec 2020 22:05:20

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2020-12-26T17:05:13', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b31cebc3-f815-4a84-b950-f26d4d79beff'	System	26 Dec 2020 22:05:20
User entered 'No (N)'	System	26 Dec 2020 22:05:20

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2020-12-26T17:05:16', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b31cebc3-f815-4a84-b950-f26d4d79beff'	System	26 Dec 2020 22:05:20
User entered '26 Dec 2020 17:05:16'	System	26 Dec 2020 22:05:20

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-01-04T10:27:57', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1d0d66b8-2dca-468b-86f5-b13865aed12d'	System	04 Jan 2021 15:28:11
User entered 'No (N)'	System	04 Jan 2021 15:28:11

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-01-04T10:28:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1d0d66b8-2dca-468b-86f5-b13865aed12d'	System	04 Jan 2021 15:28:11
User entered 'No (N)'	System	04 Jan 2021 15:28:11

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-01-04T10:28:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1d0d66b8-2dca-468b-86f5-b13865aed12d'	System	04 Jan 2021 15:28:11
User entered '04 Jan 2021 10:28:02'	System	04 Jan 2021 15:28:11

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-01-09T00:31:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1b5c468-d3ff-420c-ba99-b4ec9cfb0ab2'	System	09 Jan 2021 05:31:49
User entered 'No (N)'	System	09 Jan 2021 05:31:49

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-01-09T00:31:44', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1b5c468-d3ff-420c-ba99-b4ec9cfb0ab2'	System	09 Jan 2021 05:31:49
User entered 'No (N)'	System	09 Jan 2021 05:31:49

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-01-09T00:31:46', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'b1b5c468-d3ff-420c-ba99-b4ec9cfb0ab2'	System	09 Jan 2021 05:31:49
User entered '09 Jan 2021 00:31:46'	System	09 Jan 2021 05:31:49

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-01-18T12:09:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'ddc3bbe1-fa61-47c0-8c25-0f073f673ad2'	System	18 Jan 2021 17:09:08
User entered 'No (N)'	System	18 Jan 2021 17:09:08

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-01-18T12:09:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'ddc3bbe1-fa61-47c0-8c25-0f073f673ad2'	System	18 Jan 2021 17:09:08
User entered 'No (N)'	System	18 Jan 2021 17:09:08

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-01-18T12:09:04', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'ddc3bbe1-fa61-47c0-8c25-0f073f673ad2'	System	18 Jan 2021 17:09:08
User entered '18 Jan 2021 12:09:04'	System	18 Jan 2021 17:09:08

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 (12b7f2928c98d306)', Time: '2021-01-23T08:45:58', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e89436c-d549-4a29-ac37-bdbbeb2d52e4'	System	23 Jan 2021 13:46:07
User entered 'No (N)'	System	23 Jan 2021 13:46:07

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-01-23T08:46:02', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e89436c-d549-4a29-ac37-bdbbeb2d52e4'	System	23 Jan 2021 13:46:07
User entered 'No (N)'	System	23 Jan 2021 13:46:07

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-01-23T08:46:05', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '1e89436c-d549-4a29-ac37-bdbbeb2d52e4'	System	23 Jan 2021 13:46:07
User entered '23 Jan 2021 08:46:05'	System	23 Jan 2021 13:46:07

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-01-30T11:19:41', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '9baf7b4c-cd2e-4c65-9ae9-3c61a6157117'	System	30 Jan 2021 16:19:46
User entered 'No (N)'	System	30 Jan 2021 16:19:46

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-01-30T11:19:43', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '9baf7b4c-cd2e-4c65-9ae9-3c61a6157117'	System	30 Jan 2021 16:19:46
User entered 'No (N)'	System	30 Jan 2021 16:19:46

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-01-30T11:19:45', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '9baf7b4c-cd2e-4c65-9ae9-3c61a6157117'	System	30 Jan 2021 16:19:46
User entered '30 Jan 2021 11:19:45'	System	30 Jan 2021 16:19:46

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 (12b7f2928c98d306)', Time: '2021-02-07T01:14:27', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7dfecae4-3ac6-4051-bd05-cf73d70bb013'	System	07 Feb 2021 06:14:35
User entered 'No (N)'	System	07 Feb 2021 06:14:35

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-02-07T01:14:29', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7dfecae4-3ac6-4051-bd05-cf73d70bb013'	System	07 Feb 2021 06:14:35
User entered 'No (N)'	System	07 Feb 2021 06:14:35

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-02-07T01:14:31', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '7dfecae4-3ac6-4051-bd05-cf73d70bb013'	System	07 Feb 2021 06:14:35
User entered '07 Feb 2021 01:14:31'	System	07 Feb 2021 06:14:35

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 (12b7f2928c98d306)', Time: '2021-02-14T12:49:22', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '71f7a2d0-170a-47ed-8a91-f42c6fba9063'	System	14 Feb 2021 17:49:28
User entered 'No (N)'	System	14 Feb 2021 17:49:28

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-02-14T12:49:24', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '71f7a2d0-170a-47ed-8a91-f42c6fba9063'	System	14 Feb 2021 17:49:28
User entered 'No (N)'	System	14 Feb 2021 17:49:28

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-02-14T12:49:26', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '71f7a2d0-170a-47ed-8a91-f42c6fba9063'	System	14 Feb 2021 17:49:28
User entered '14 Feb 2021 12:49:26'	System	14 Feb 2021 17:49:28

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 (12b7f2928c98d306)', Time: '2021-02-20T08:30:23', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2d9978d0-30eb-4a26-ae00-b35a0c5888a8'	System	20 Feb 2021 13:30:32
User entered 'No (N)'	System	20 Feb 2021 13:30:32

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-02-20T08:30:25', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2d9978d0-30eb-4a26-ae00-b35a0c5888a8'	System	20 Feb 2021 13:30:32
User entered 'No (N)'	System	20 Feb 2021 13:30:32

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-02-20T08:30:27', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2d9978d0-30eb-4a26-ae00-b35a0c5888a8'	System	20 Feb 2021 13:30:32
User entered '20 Feb 2021 08:30:27'	System	20 Feb 2021 13:30:32

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-02-28T16:57:51-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e9aae455-5713-42bf-a999-89ff9648388a'	System	28 Feb 2021 21:58:03
User entered 'No (N)'	System	28 Feb 2021 21:58:03

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-02-28T16:57:53-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e9aae455-5713-42bf-a999-89ff9648388a'	System	28 Feb 2021 21:58:03
User entered 'No (N)'	System	28 Feb 2021 21:58:03

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-02-28T16:57:58-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'e9aae455-5713-42bf-a999-89ff9648388a'	System	28 Feb 2021 21:58:03
User entered '28 Feb 2021 16:57:58'	System	28 Feb 2021 21:58:03

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-03-06T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a204ed6d-f510-4159-9cc6-e35eb86dae0f'	System	06 Mar 2021 05:02:51
User entered 'No (N)'	System	06 Mar 2021 05:02:51

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-03-06T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a204ed6d-f510-4159-9cc6-e35eb86dae0f'	System	06 Mar 2021 05:02:51
User entered 'No (N)'	System	06 Mar 2021 05:02:51

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-03-06T00:01:27-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'a204ed6d-f510-4159-9cc6-e35eb86dae0f'	System	06 Mar 2021 05:02:51
User entered '06 Mar 2021 00:01:27'	System	06 Mar 2021 05:02:51

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-03-13T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '355d73d2-2179-45b8-88aa-b57f1f678c20'	System	13 Mar 2021 05:02:27
User entered 'No (N)'	System	13 Mar 2021 05:02:27

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-03-13T00:01:30-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '355d73d2-2179-45b8-88aa-b57f1f678c20'	System	13 Mar 2021 05:02:27
User entered 'No (N)'	System	13 Mar 2021 05:02:27

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-03-13T00:01:32-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '355d73d2-2179-45b8-88aa-b57f1f678c20' User entered '13 Mar 2021 00:01:32'	System	13 Mar 2021 05:02:27
	System	13 Mar 2021 05:02:27

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-03-21T18:48:17-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3a0eda03-073e-4eda-9e25-4ac244a8e193'	System	21 Mar 2021 22:48:25
User entered 'No (N)'	System	21 Mar 2021 22:48:25

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-03-21T18:48:19-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3a0eda03-073e-4eda-9e25-4ac244a8e193'	System	21 Mar 2021 22:48:25
User entered 'No (N)'	System	21 Mar 2021 22:48:25

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-03-21T18:48:21-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '3a0eda03-073e-4eda-9e25-4ac244a8e193'	System	21 Mar 2021 22:48:25
User entered '21 Mar 2021 18:48:21'	System	21 Mar 2021 22:48:25

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-04-03T01:52:28-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6a1cab3c-5479-4be7-86d1-b1fa74e59c2d'	System	03 Apr 2021 06:02:26
User entered 'No (N)'	System	03 Apr 2021 06:02:26

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-04-03T01:52:30-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6a1cab3c-5479-4be7-86d1-b1fa74e59c2d'	System	03 Apr 2021 06:02:26
User entered 'No (N)'	System	03 Apr 2021 06:02:26

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-04-03T01:52:34-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '6a1cab3c-5479-4be7-86d1-b1fa74e59c2d'	System	03 Apr 2021 06:02:26
User entered '03 Apr 2021 01:52:34'	System	03 Apr 2021 06:02:26

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (12b7f2928c98d306)', Time: '2021-04-10T10:01:10-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2b8a25f9-1fcd-4066-ae64-c18522f577d3'	System	10 Apr 2021 14:01:20
User entered 'No (N)'	System	10 Apr 2021 14:01:20

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (12b7f2928c98d306)', Time: '2021-04-10T10:01:13-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2b8a25f9-1fcd-4066-ae64-c18522f577d3'	System	10 Apr 2021 14:01:20
User entered 'No (N)'	System	10 Apr 2021 14:01:20

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-04-10T10:01:16-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '2b8a25f9-1fcd-4066-ae64-c18522f577d3'	System	10 Apr 2021 14:01:20
User entered '10 Apr 2021 10:01:16'	System	10 Apr 2021 14:01:20

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 (3bdf4ba766f70cc5)', Time: '2021-04-19T11:13:28-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0ea3caab-d151-40ed-9db9-22a8061d05d0'	System	19 Apr 2021 15:13:35
User entered 'No (N)'	System	19 Apr 2021 15:13:35

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (3bdf4ba766f70cc5)', Time: '2021-04-19T11:13:29-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0ea3caab-d151-40ed-9db9-22a8061d05d0'	System	19 Apr 2021 15:13:35
User entered 'No (N)'	System	19 Apr 2021 15:13:35

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bdf4ba766f70cc5)', Time: '2021-04-19T11:13:32-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '0ea3caab-d151-40ed-9db9-22a8061d05d0'	System	19 Apr 2021 15:13:35
User entered '19 Apr 2021 11:13:32'	System	19 Apr 2021 15:13:35

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (3bdf4ba766f70cc5)', Time: '2021-04-24T00:10:49-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd4eb562e-ab63-4495-b972-e5bed689be3a'	System	24 Apr 2021 04:11:07
User entered 'No (N)'	System	24 Apr 2021 04:11:07

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (3bdf4ba766f70cc5)', Time: '2021-04-24T00:10:51-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd4eb562e-ab63-4495-b972-e5bed689be3a'	System	24 Apr 2021 04:11:07
User entered 'No (N)'	System	24 Apr 2021 04:11:07

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bdf4ba766f70cc5)', Time: '2021-04-24T00:10:54-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: 'd4eb562e-ab63-4495-b972-e5bed689be3a'	System	24 Apr 2021 04:11:07
User entered '24 Apr 2021 00:10:54'	System	24 Apr 2021 04:11:07

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (3bdf4ba766f70cc5)', Time: '2021-05-03T16:00:04-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '26e63ec2-29e2-4b41-851f-361fc621aec9'	System	03 May 2021 20:00:41
User entered 'Yes (Y)'	System	03 May 2021 20:00:41

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Have you been exposed to someone with 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 (3bdf4ba766f70cc5)', Time: '2021-05-03T16:00:08-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '26e63ec2-29e2-4b41-851f-361fc621aec9'	System	03 May 2021 20:00:41
User entered 'No (N)'	System	03 May 2021 20:00:41

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[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 (3bdf4ba766f70cc5)', Time: '2021-05-03T16:00:11-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '26e63ec2-29e2-4b41-851f-361fc621aec9'	System	03 May 2021 20:00:41
User entered 'No (N)'	System	03 May 2021 20:00:41

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

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 (3bdf4ba766f70cc5)', Time: '2021-05-03T16:00:17-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '26e63ec2-29e2-4b41-851f-361fc621aec9'	System	03 May 2021 20:00:41
User entered 'Yes (Y)'	System	03 May 2021 20:00:41

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

Please 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 (3bdf4ba766f70cc5)', Time: '2021-05-03T16:00:25-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '26e63ec2-29e2-4b41-851f-361fc621aec9'	System	03 May 2021 20:00:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 20:00:41

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3bdf4ba766f70cc5)', Time: '2021-05-03T16:00:27-04:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '26e63ec2-29e2-4b41-851f-361fc621aec9' User entered '03 May 2021 16:00:27'	System	03 May 2021 20:00:41
	System	03 May 2021 20:00:41

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:19:34

US3412153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:19:34
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:19:34

US3412153

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:37:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-02-28T16:58:16-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '9d5e2e31-ce93-465c-9644-3be741ccd22e'	System	28 Feb 2021 21:58:22
User entered 'No (N)'	System	28 Feb 2021 21:58:22

US3412153

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:37:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:52:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12b7f2928c98d306)', Time: '2021-02-28T16:58:19-05:00', User OID: 'PatientReportedOutcome (US3412153)', ODM File OID: '9d5e2e31-ce93-465c-9644-3be741ccd22e' User entered '28 Feb 2021 16:58:19'	System	28 Feb 2021 21:58:22
	System	28 Feb 2021 21:58:22

US3412153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:47:03
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Nov 2020 21:50:13

US3412153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:25
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	27 Nov 2020 10:50:44
DataPoint Verified.	(b) (4)	17 Nov 2020 19:47:03
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DUE TO ADVERSE EVENT FOR CHRONIC HTN THAT IS ONGOING TO END OF STUDY SOME OF SUBJECTS VISIT DATES COULD BE OFF.' (Site from System).	Melissa Fuson (b) (4)	11 Nov 2020 13:40:28
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Nov 2020 21:50:13
User entered '5 Nov 2020'	Mason Urban (b) (4)	05 Nov 2020 21:50:13

US3412153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:47:03
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	05 Nov 2020 21:50:13

US3412153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:47:03
User entered empty.	Mason Urban (b) (4) (b) (4)	05 Nov 2020 21:50:13

US3412153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:47:07
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Nov 2020 21:50:19

US3412153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:10:48
User entered 'I'	System	05 Nov 2020 21:50:19

US3412153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:31:51
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Dec 2020 18:47:51

US3412153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:31:51
User entered '9 Dec 2020'	Mason Urban (b) (4) (b) (4)	09 Dec 2020 18:47:51

US3412153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:31:51
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	09 Dec 2020 18:47:51

US3412153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:31:51
User entered empty.	Mason Urban (b) (4) (b) (4)	09 Dec 2020 18:47:51

US3412153

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:31:31
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Dec 2020 18:47:56

US3412153

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User entered '1'	System	09 Dec 2020 18:47:56

US3412153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:06
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	08 Jan 2021 17:47:47

US3412153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:06
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 15:43:08
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'SCHEDULED IN CLINICAL CONDUCTOR FOR 8 JAN 2021' (Site from System).	Mason Urban (b) (4) (b) (4)	08 Jan 2021 17:48:10
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Jan 2021 17:47:47
User entered '8 Jan 2021'	Mason Urban (b) (4) (b) (4)	08 Jan 2021 17:47:47

US3412153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:06
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	08 Jan 2021 17:47:47

US3412153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:06
User entered empty.	Mason Urban (b) (4) (b) (4)	08 Jan 2021 17:47:47

US3412153

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:03:10
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	08 Jan 2021 17:52:40

US3412153

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User entered '1'	System	08 Jan 2021 17:52:40

US3412153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:53:59
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	02 Feb 2021 17:21:02

US3412153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:53:59
User entered '2 Feb 2021'	Mason Urban (b) (4) (b) (4)	02 Feb 2021 17:21:02

US3412153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:53:59
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	02 Feb 2021 17:21:02

US3412153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:53:59
User entered empty.	Mason Urban (b) (4) (b) (4)	02 Feb 2021 17:21:02

US3412153

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:54:02
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	02 Feb 2021 17:21:12

US3412153

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:38:00
User entered '1'	System	02 Feb 2021 17:21:12

US3412153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:56:03
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:54:53

US3412153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:56:03
User entered '02 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:54:53

US3412153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[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 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:56:03
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:54:53

US3412153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered 'VISIT4'	System	02 Mar 2021 19:54:53

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered empty.	System	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered empty.	System	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered empty.	System	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered empty.	System	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:19:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered empty.	System	30 Mar 2021 15:04:10

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33

US3412153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33

US3412153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:56:42
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:54:59

US3412153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:56:42
User entered empty.	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:54:59

US3412153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:57:18
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:57:46

US3412153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:57:18
User entered '02 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:57:46

US3412153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:57:18
User entered '12:37'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:57:46

US3412153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered '02 Mar 2021 12:37'	System	02 Mar 2021 19:57:46

US3412153

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:56:15
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 19:57:50

US3412153

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:49:33
User entered '1'	System	02 Mar 2021 19:57:50

US3412153

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:51:33

US3412153

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	01 Apr 2021 15:51:41
User entered '01 Apr 2021' reason for change: Data Entry Error	System	01 Apr 2021 15:51:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 15:51:33
User entered '01 Apr ' (non-conformant).	System	01 Apr 2021 15:51:33
	(b) (4), (b) (6)	

US3412153

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:51:33

US3412153

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:34:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:51:33

US3412153

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:56:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:27:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:51:44

US3412153

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:51:44

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:00:17

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:25
User entered '02 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:00:17

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[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 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:25
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:00:17

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 20:00:17

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered '13 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:39
User entered '0'	Andrea Newlands (b) (4)	18 Mar 2021 16:27:27
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:40:14

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:33:36
User closed query 'Amendment 6 - please complete' (Site from CRA).	(b) (4)	19 Mar 2021 15:33:33
Query 'Amendment 6 - please complete' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	18 Mar 2021 16:27:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	18 Mar 2021 16:27:27
User opened query 'Amendment 6 - please complete' (Site from CRA).	Andrea Newlands (b) (4)	18 Mar 2021 16:27:27
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	08 Mar 2021 16:52:26
	System	06 Mar 2021 11:40:14

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered '02 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:33
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered empty.	System	02 Mar 2021 20:04:31

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:42
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:51

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:42
User entered '02 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:51

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:42
User entered '12:37'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:04:51

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '02 Mar 2021 12:37'	System	02 Mar 2021 20:04:51

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:46
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:05:01

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:46
User entered '02 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:05:01

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:51:46
User entered '12:40'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 20:05:01

US3412153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:32

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:59:34
User entered '02 Mar 2021 12:40'	System	02 Mar 2021 20:05:01

US3412153

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:37:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:35
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		16 Apr 2021 11:06:51
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:45:22
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 13:33:04
User signature succeeded.	Richard Powell (b) (4) (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 14:01:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:20:34
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 19:08:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:02:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:02:15
Data point term sent to Coder	System	08 Oct 2020 20:22:30
User entered 'Chronic Hypertension worsening'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '24 Sep 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User entered empty.	System	08 Oct 2020 20:21:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:58:21
User closed query 'Per DM CLR: Please review this worsening AE as it was noted as ongoing for more than 60 days. Please verify if this has returned to baseline grade and a stop date should be recorded for this AE, and if so, update accordingly. Otherwise, comment to confirm that this worsening AE is still ongoing.' (Site from DM).	(b) (4)	16 Feb 2021 16:21:06
Query 'Per DM CLR: Please review this worsening AE as it was noted as ongoing for more than 60 days. Please verify if this has returned to baseline grade and a stop date should be recorded for this AE, and if so, update accordingly. Otherwise, comment to confirm that this worsening AE is still ongoing.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	15 Feb 2021 16:26:13
DataPoint Un-verified.	(b) (4) Andrea Newlands (b) (4)	15 Feb 2021 16:26:05
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	15 Feb 2021 16:26:05
User opened query 'Per DM CLR: Please review this worsening AE as it was noted as ongoing for more than 60 days. Please verify if this has returned to baseline grade and a stop date should be recorded for this AE, and if so, update accordingly. Otherwise, comment to confirm that this worsening AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 17:54:20
DataPoint Verified.	(b) (4)	19 Oct 2020 14:01:33
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 20:21:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:58:28
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Feb 2021 16:26:21
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Feb 2021 16:26:21
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Feb 2021 16:26:05
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	15 Feb 2021 16:26:05
User entered '10 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	15 Feb 2021 16:26:05
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User entered empty.	System	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:48:43
User closed query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please update Severity as appropriate. Otherwise, clarify.' (Site from DM).		05 Nov 2020 16:13:28
Query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please update Severity as appropriate. Otherwise, clarify.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	28 Oct 2020 19:36:24
DataPoint Un-verified.	Jacob sekinger (b) (4) (b) (4)	28 Oct 2020 19:36:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	28 Oct 2020 19:36:17
User opened query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please update Severity as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:24:54
DataPoint Verified.		19 Oct 2020 14:01:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'None (NONE)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '1'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

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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 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:59:16
DataPoint Un-verified.	Andrea Newlands (b) (4)	15 Feb 2021 16:26:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	15 Feb 2021 16:26:21
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Steven Anderson (b) (4)	08 Oct 2020 20:21:50
	(b) (4)	

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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 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:01:33
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User entered '0'	System	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37
User entered '1'	System	08 Oct 2020 20:21:50

US3412153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension exacerbated - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 16:25:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 16:25:15
Data point term sent to Coder	System	13 Apr 2021 12:39:26
User entered 'worsening chronic hypertension'	Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Yes (Y)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '30 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Yes (Y)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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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)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4) (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:37:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4)	
	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:26:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:06
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:27:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'None (NONE)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:06
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '1'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:00
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '1'	Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:41
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:42:13
User entered 'Unknown (UNKNOWN)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4) (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4) (b) (4)	10 Feb 2021 17:34:53

US3412153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 12:39:08
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4) (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:37:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 12:38:03
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	10 Feb 2021 17:34:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 12:42:56
Data point term sent to Coder	(b) (4)	
User entered 'headache'	System	13 Apr 2021 12:42:27
	Andrea Newlands (b) (4)	13 Apr 2021 12:41:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
User closed query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4)	29 Apr 2021 08:34:09
Query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	27 Apr 2021 14:58:10
User opened query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:48:28
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 13:30:56
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '12 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	13 Apr 2021 12:45:32
User entered '13 Aug 2020'	(b) (4)	
	Andrea Newlands (b) (4)	13 Apr 2021 12:41:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
User entered empty.	System	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	13 Apr 2021 12:42:03
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	13 Apr 2021 12:42:03
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	13 Apr 2021 12:42:03
User entered '13 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 12:42:03
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	13 Apr 2021 12:41:56
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	13 Apr 2021 12:41:56
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
User entered empty.	System	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4)	28 Apr 2021 17:52:59
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:30
DataPoint Un-verified.	(b) (4)	(b) (4)
Signature has been broken.	Steven Anderson (b) (4)	27 Apr 2021 14:58:17
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4)	27 Apr 2021 14:58:17
DataPoint Verified.	Steven Anderson (b) (4)	27 Apr 2021 14:58:17
User signature succeeded.	(b) (4)	(b) (4)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Apr 2021 20:31:49
	(b) (4)	(b) (4)
	Richard Powell (b) (4)	16 Apr 2021 13:30:56
	(b) (4)	(b) (4)
	Andrea Newlands (b) (4)	13 Apr 2021 12:41:56
	(b) (4)	(b) (4)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Not Related (NOT RELATED)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'None (NONE)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '1'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 12:41:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

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 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:31:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
User entered '0'	System	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40
User entered '0'	System	13 Apr 2021 12:41:56

US3412153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:37:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:36:40

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:37:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:35
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:28
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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)	19 Feb 2021 05:22:19
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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 'per safety call source, this entry was an error by the patient.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:13:10
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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)	17 Feb 2021 18:39:04
DataPoint Verified.		25 Aug 2020 18:42:35
User entered 'Yes (Y)'		18 Aug 2020 17:46:39

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 14:28:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 14:28:47
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Aug 2020 19:04:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Aug 2020 19:04:49
Data point term sent to Coder	System	18 Aug 2020 17:48:27
User entered 'Lisinopril-Hydrochlorothiazide'	(b) (4), (b) (6)	18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'No (N)'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'HYPERTENSION'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered '12.5/20'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'mg (mg)'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'once daily (QD)'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'Oral (ORAL)'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		19 Aug 2020 12:46:01
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.'		18 Aug 2020 20:49:22
answered with 'NA' (Site from System).		
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	18 Aug 2020 17:48:15
User entered 'UN Feb 2020'	(b) (4), (b) (6)	18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered '0'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
DataPoint Un-verified.	Steven Anderson (b) (4)	08 Oct 2020 20:26:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	08 Oct 2020 20:26:46
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'Yes (Y)'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
DataPoint Un-verified.	Steven Anderson (b) (4)	08 Oct 2020 20:26:46
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 20:26:46
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'No (N)'		18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User entered '1'	System	18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User entered '1'	System	18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:52
User entered '804 (804)'	System	18 Aug 2020 17:48:15

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:07:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:07:22
Data point term sent to Coder	System	18 Aug 2020 17:49:27
User entered 'VENTOLIN MDI'	(b) (4), (b) (6)	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'No (N)'		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'ASTHMA'	(b) (4), (b) (6)	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:15:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4)	28 Oct 2020 05:20:53
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	23 Oct 2020 15:11:19
DataPoint Un-verified.	Jacob sekinger (b) (4) (b) (4)	23 Oct 2020 15:11:11
User entered '190' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	23 Oct 2020 15:11:11
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:54:15
DataPoint Verified.	(b) (4)	25 Aug 2020 18:43:21
User entered '2'	(b) (4)	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:15:42
DataPoint Un-verified.	Jacob sekinger (b) (4)	23 Oct 2020 15:11:11
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Jacob sekinger (b) (4)	23 Oct 2020 15:11:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'puff (PUFF)'		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'as needed (PRN)'		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4)	25 Aug 2020 18:43:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 12:46:10
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.'	(b) (4), (b) (6)	18 Aug 2020 20:49:27
answered with 'NA' (Site from System).		
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	18 Aug 2020 17:48:56
User entered 'UN UNK 2012'	(b) (4), (b) (6)	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered '0'		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'Yes (Y)'		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 18:43:21
User entered 'No (N)'		18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 17:48:56

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: HYZAAR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 04:49:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 04:49:28
Data point term sent to Coder	System	08 Oct 2020 20:29:47
User entered 'Hyzaar/hydrochlorothiazide'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered 'Hypertension'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered '50/12.5'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered 'once daily (QD)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered 'Oral (ORAL)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered '24 Sep 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:00:19
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 20:29:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 20:29:31
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:31
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 20:29:27
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 20:29:27

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:22:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:22:49
Data point term sent to Coder	System	18 Feb 2021 13:11:05
User entered 'influenza vaccination'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'influenza preophylaxis'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered '0.5'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'mL (mL)'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered empty.	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered empty.	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered empty.	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered '07 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered '0'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered '07 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:00:11
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User entered empty.	System	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User entered empty.	System	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:21:59
User entered empty.	System	18 Feb 2021 13:10:13

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 13:11:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:11:04
Data point term sent to Coder User entered 'carvedilol'	System Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 13:09:40 13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'hypertension'	Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '6.25'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'mg (mg)'	Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'twice daily (BID)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Oral (ORAL)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '30 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:08:42

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 13:34:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:34:16
Data point term sent to Coder User entered 'furosemide'	System Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 13:32:09 13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'hypertension'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '20'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'mg (mg)'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '30 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '0'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:33:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 13:31:44

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:37:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:20:09
DataPoint Un-verified.	Andrea Newlands (b) (4)	13 Apr 2021 13:31:53
Signature has been broken.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 13:31:53
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:53:45
User entered 'No (N)'		18 Aug 2020 17:49:17

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:32

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '10 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 15:22:17

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:06
DataPoint Verified.	(b) (4)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'echocardiogram'	(b) (4) Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 15:22:17

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 15:22:17

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:32

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:35:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 15:22:17

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered '30 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 15:22:33

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'cardiac angiogram'	Andrea Newlands (b) (4)	13 Apr 2021 15:22:33

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:32

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered 'Adverse Event (AE)'	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 15:22:33

US3412153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:32

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:56
User entered empty.	(b) (4) Andrea Newlands (b) (4)	13 Apr 2021 15:22:33