

US3412151 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3412151

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:26:32

Generated On: 09 Jun 2021 17:36:59

Participant ID

US3412151

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

tb

US3412151

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:51:49

Generated On: 09 Jun 2021 17:36:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

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 04:51:48

Generated On: 09 Jun 2021 17:36:59

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

Condition	OSTEOARTHRITIS - BOTH KNEES,LEFT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:51:49

Generated On: 09 Jun 2021 17:36:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:18 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:18
Height (<i>xxx.x</i>)	171.5 cm
Weight (<i>xxx.x</i>)	114.0 kg
BMI (<i>xxx.x</i>)	38.75936 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 04:51:48

Generated On: 09 Jun 2021 17:36:59

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

06 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: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:51:48

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify LIVES WITH ESSENTIAL WORKER

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 04:51:48

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

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Folder: Visit 1 Day 1

Form: Visit Date

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

Generated On: 09 Jun 2021 17:36:59

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 02:39:58

Generated On: 09 Jun 2021 17:36:59

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

What was the participant's randomization number? 184925

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 02:39:58

Generated On: 09 Jun 2021 17:36:59

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 02:39:58

Generated On: 09 Jun 2021 17:36:59

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>)	09:18 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 09:18
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 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 02:39:58

Generated On: 09 Jun 2021 17:36:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:06 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 11:06
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 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 02:39:58

Generated On: 09 Jun 2021 17:36:59

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy) _____

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

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Folder: Visit 1 Day 1

Form: Exposure

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

Generated On: 09 Jun 2021 17:36:59

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) 10:35 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 10:35

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 02:39:58

Generated On: 09 Jun 2021 17:36:59

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 06 AUG 2020

Collection time (*00:00-23:59*) 09:55 (24 HR)

Collection date and time (derived) 06 AUG 2020 09:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

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

Generated On: 09 Jun 2021 17:36:59

Collection date (<i>dd MMM yyyy</i>)			06 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	10:00	06 AUG 2020 10:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

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

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 97.1 °F

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

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

PC Time Stamp 06 AUG 2020 11:15

PC Open Date & Time 06 AUG 2020 10:55

PC Close Date & Time 06 AUG 2020 13:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 96.5 °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 19:05
PC Open Date & Time 06 AUG 2020 14:20
PC Close Date & Time 07 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

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

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

PC Time Stamp	07 AUG 2020 19:21
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

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	98.0 °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	08 AUG 2020 19:02
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

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

PC Time Stamp	09 AUG 2020 19:58
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.5 °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 10 AUG 2020 19:04

PC Open Date & Time 10 AUG 2020 12:00

PC Close Date & Time 11 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

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** 97.9 °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 11 AUG 2020 19:01
PC Open Date & Time 11 AUG 2020 12:00
PC Close Date & Time 12 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.9 °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 12 AUG 2020 18:55

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 11:16
PC Open Date & Time	06 AUG 2020 10:55
PC Close Date & Time	06 AUG 2020 13:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 19:06

PC Open Date & Time

06 AUG 2020 14:20

PC Close Date & Time

07 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 19:22

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 19:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 19:59

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 19:05

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 19:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

12 AUG 2020 18:56

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

No

Yes

PC Time stamp	06 AUG 2020 11:17
PC Open Date & Time	06 AUG 2020 10:55
PC Close Date & Time	06 AUG 2020 13:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

No
Yes

PC Time stamp	06 AUG 2020 19:07
PC Open Date & Time	06 AUG 2020 14:20
PC Close Date & Time	07 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 19:23
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

Yes

PC Time stamp	08 AUG 2020 19:03
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

Yes

PC Time stamp	09 AUG 2020 20:00
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 19:06
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 18:56
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:59

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 19:21
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

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

Generated On: 09 Jun 2021 17:36:59

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 03 SEP 2020

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

Folder OID VISIT2

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

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

Generated On: 09 Jun 2021 17:36:59

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>)	07:15 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 07:15
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

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

Generated On: 09 Jun 2021 17:36:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:36 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 08:36
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3412151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

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

Generated On: 09 Jun 2021 17:36:59

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.

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

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

Generated On: 09 Jun 2021 17:36:59

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 08:03 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 08:03

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

US3412151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

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

Generated On: 09 Jun 2021 17:36:59

Was the sample collected? Yes
No

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

Collection time (*00:00-23:59*) 07:37 (24 HR)

Collection date and time (derived) 03 SEP 2020 07:37

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

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

Generated On: 09 Jun 2021 17:36:59

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	07:39	03 SEP 2020 07:39
Nasopharyngeal Swab 2	No		

US3412151

Folder: Visit 2 Day 29 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp 03 SEP 2020 08:43
PC Open Date & Time 03 SEP 2020 08:23
PC Close Date & Time 03 SEP 2020 10:53

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 98.1 °F

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

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

PC Time Stamp 03 SEP 2020 18:53
PC Open Date & Time 03 SEP 2020 11:48
PC Close Date & Time 04 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °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	04 SEP 2020 18:05
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

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	98.5 °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	05 SEP 2020 19:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

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):

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

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

PC Time Stamp 06 SEP 2020 18:42

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

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	98.0 °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	07 SEP 2020 18:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

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	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 18:20
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 09 SEP 2020 18:57

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 08:44

PC Open Date & Time

03 SEP 2020 08:23

PC Close Date & Time

03 SEP 2020 10:53

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

03 SEP 2020 18:53

PC Open Date & Time

03 SEP 2020 11:48

PC Close Date & Time

04 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 18:06

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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	05 SEP 2020 19:23
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 18:43
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 18:35
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

08 SEP 2020 18:21

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 18:58
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

No

Yes

PC Time stamp	03 SEP 2020 08:44
PC Open Date & Time	03 SEP 2020 08:23
PC Close Date & Time	03 SEP 2020 10:53

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

No
Yes

PC Time stamp	03 SEP 2020 18:54
PC Open Date & Time	03 SEP 2020 11:48
PC Close Date & Time	04 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 18:07
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 19:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 18:43
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 18:37
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 18:21
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 18:59
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:51:48

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 43 (1)

Form: Safety Call

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

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Safety Call Day 43 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 50 (1)

Form: Safety Call

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

Generated On: 09 Jun 2021 17:36:59

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3412151

Folder: Safety Call Day 50 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

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

Generated On: 09 Jun 2021 17:36:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

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

Generated On: 09 Jun 2021 17:36:59

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) _____

US3412151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

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

Generated On: 09 Jun 2021 17:36:59

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.

US3412151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

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

Generated On: 09 Jun 2021 17:36:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 01 OCT 2020

Collection time (*00:00-23:59*) 07:50 (24 HR)

Collection date and time (derived) 01 OCT 2020 07:50

US3412151

Folder: Visit 3 Day 57 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 21:58:29

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

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

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 16:13:18

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

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

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 22 OCT 2020 12:00:47

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

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

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 NOV 2020 13:58:27
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 NOV 2020 13:01:48
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 21 NOV 2020 08:11:24

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

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

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 14:49:53
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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	05 DEC 2020 08:06:52
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 131

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

No

Yes

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

No

Yes

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

Date and time of submission 12 DEC 2020 10:36:09

Patient Cloud Open Date & Time 12 DEC 2020 00:01

Patient Cloud Close Date & Time 16 DEC 2020 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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	19 DEC 2020 18:05:47
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 07:56:27
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 04 JAN 2021 11:22:16

Patient Cloud Open Date & Time 02 JAN 2021 00:01

Patient Cloud Close Date & Time 06 JAN 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 10 JAN 2021 10:14:41

Patient Cloud Open Date & Time 09 JAN 2021 00:01

Patient Cloud Close Date & Time 13 JAN 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 08:52:58
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 20:05:12

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

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

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 12:00:44
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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	06 FEB 2021 18:36:14
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 20:49:32
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 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	22 FEB 2021 13:48:39
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

27 FEB 2021 17:25:18

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

DAY 215

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

No

Yes

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

No

Yes

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

Date and time of submission 08 MAR 2021 13:00:37

Patient Cloud Open Date & Time 06 MAR 2021 00:01

Patient Cloud Close Date & Time 10 MAR 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 07:27:59
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	20 MAR 2021 11:33:35
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 MAR 2021 11:24:38
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3412151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:36:59

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		27 FEB 2021 17:25:30

US3412151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:33:17

Generated On: 09 Jun 2021 17:36:59

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3412151

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:33:17

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3412151

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 31 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3412151

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3412151

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 MAR 2021

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

Folder OID VISIT4

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

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) _____

US3412151

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

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.

US3412151

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 04 MAR 2021

Collection time (*00:00-23:59*) 07:36 (24 HR)

Collection date and time (derived) 04 MAR 2021 07:36

US3412151

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3412151

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 1 APR 2021

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

Comments LEFT VM ON 01 APR 2021.
CALLED BACK 01 APR 2021.

If Contact Not Made, please provide Comments

US3412151

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:26:33

Generated On: 09 Jun 2021 17:36:59

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3412151

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:59

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"/>

US3412151

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:36:59

Generate Next COVID-19 Assessment

Yes

No

US3412151

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:26:32

Generated On: 09 Jun 2021 17:36:59

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 4 JAN 2021

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

Folder OID UNBLND_DECIDE

US3412151

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:26:32

Generated On: 09 Jun 2021 17:36:59

Date of updated informed consent (*dd MMM yyyy*) 4 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*) 4 JAN 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3412151

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:26:32

Generated On: 09 Jun 2021 17:36:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 4 JAN 2021

Collection time (*00:00-23:59*) 09:51 (24 HR)

Collection date and time (derived) 4 JAN 2021 09:51

US3412151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:26:32

Generated On: 09 Jun 2021 17:36:59

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 4 JAN 2021

Collection time (*00:00 - 23:59*) 09:59

Collection Date and Time (derived) 4 JAN 2021 09:59

US3412151

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:32:36

Generated On: 09 Jun 2021 17:36:59

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

AEID USA-US061-2021-MRNA-1273-P30
1000017

Adverse event WORSENING OF AORTIC
STENOSIS

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) 5 FEB 2021

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

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

End time (00:00-23:59) _____

AE End Date and Time (derived) _____

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 31 MAR 2021

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

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EAB) (1725)

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event True

Relationship to investigational product Not Related
 Related
 Not Applicable

Relationship to Study Procedure Not Related
 Related
 Not Applicable

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

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

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

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

Narrative

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

SPOKE TO SUBJECT ON
23-FEB-2021 AT 1440. SUBJECT
WAS TO HAVE LEFT SHOULDER
JOINT REPLACEMENT. HE WAS
NOT ABLE TO HAVE SURGERY
DUE TO NEW FINDINGS ON
ECHOCARDIOGRAM (5 FEB
2021) THAT AORTIC STENOSIS
HAS WORSENERED FROM
MODERATE TO SEVERE
CLASSIFICATION. SUBJECT
WILL SEE CARDIOLOGIST ON
MARCH 4TH. AS OF RIGHT NOW
SHOULDER SURGERY
POST-PONED AND POSSIBLE
AORTIC VALVE
REPLACEMENT.

PATIENT HAD AORTIC VALVE
REPLACEMENT SURGERY ON
31 MAR 2021. PT NOT FULLY
RECOVERED AS OF 01 APR 2021.
SPOKE TO PATIENT'S SPOUSE.
UPDATE: SITE WAS INFORMED
TODAY THAT SUBJECT HAS
PASSED AWAY. SITE DOES NOT
KNOW FULL DETAILS,
HOWEVER, IT SEEMS THAT IT
WAS DUE TO THE STROKE. SIT
HAS REQUESTED MEDICAL
RECORDS AND WILL UPDATE
ACCORDINGLY

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

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

AEID	USA-US061-2021-MRNA-1273-P30 1000017
Adverse event	STROKE
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)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

PATIENT WAS IN FOR HEART VALVE REPLACEMENT ON 31 MAR 2021. FOLLOWING SURGERY SOMETIME, PATIENT HAD A STROKE WHILE STILL IN HOSPITAL. PATIENT IS CURRENTLY IN ICU AS OF 01 APR 2021. SPOKE TO PATIENT'S SPOUSE DURING ROUTINE SAFETY CALL DAY 239. THIS SAE HAS RESULTED IN SUBJECTS DEATH. SITE KNOWS MINIMAL INFORMATION HOWEVER, IT SEEMS THE STROKE IS THE CAUSE. SITE REQUESTED FOR MEDICAL RECORDS AND WILL UPDATE INFORMATION AS WE LEARN MORE

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

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:36:25

Generated On: 09 Jun 2021 17:36:59

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

Yes

No

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

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 81

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

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Name of Medication LOSARTAN

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Name of Medication ROSUVASTATIN

Prophylaxis Yes
No

Indication HYPERLIPIDEMIA

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
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

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Name of Medication IRBASARTAN

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 150

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2017

Start date completely unknown False

Ongoing? Yes
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

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication SOLICITED INJECTION SITE
PAIN

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:18:31

Generated On: 09 Jun 2021 17:36:59

	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) 07 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 07 AUG 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:36:26

Generated On: 09 Jun 2021 17:36:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 FEB 2021	ECHOCARDIOGRAM	Diagnostic	
31 MAR 2021	AORTIC VALVE REPLACEMENT	Adverse Event	

US3412151

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:36:59

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

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Apr 2021 14:41:29

Generated On: 09 Jun 2021 17:36:59

Date of study discontinuation/completion (dd MMM yyyy) 02 APR 2021

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) 02 APR 2021

Was autopsy performed?

Yes

No

Unknown

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:41:29

Generated On: 09 Jun 2021 17:36:59

SAEID	USA-US061-2021-MRNA-1273-P30 1000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:41:29

Generated On: 09 Jun 2021 17:36:59

SAEID	USA-US061-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/APR/2021 11:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:41:29

Generated On: 09 Jun 2021 17:36:59

SAEID	USA-US061-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 10:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:41:29

Generated On: 09 Jun 2021 17:36:59

SAEID	USA-US061-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 15:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

Audit

US3412151 (Prod: New Horizons Clinical Research)

US3412151

Form: Participant Creation

Generated On: 09 Jun 2021 17:36:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'US3412151'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 12:44:32

US3412151

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:49:57

US3412151

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 12:44:33

US3412151

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:49:57

US3412151

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'SCRN'	System	06 Aug 2020 14:49:57

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 12:44:34

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '71'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'YEARS'	System	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '71'	System	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '1'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:09

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'Aug 2020'	System	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '2020'	System	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:41

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 12:44:33

US3412151

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '1'	System	06 Aug 2020 14:50:52

US3412151

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:36:59

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:50:52

US3412151

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:36:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:16:52

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:19:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:19:17
Data point term sent to Coder	System	07 Aug 2020 16:18:25
User entered 'Sleep Apnea'	(b) (4), (b) (6)	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'Jan 2016'	System	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '2016'	System	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:17:36

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:19:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:19:16
Data point term sent to Coder	System	07 Aug 2020 16:18:28
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'Jan 2017'	System	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '2017'	System	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:18:01

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
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)	07 Aug 2020 16:21:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:21:17
Data point term sent to Coder	System	07 Aug 2020 16:19:30
User entered 'Hypertension'	(b) (4), (b) (6)	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'Jan 2010'	System	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '2010'	System	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:19:03

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:08:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 14:08:09
Data point term sent to Coder	System	16 Mar 2021 19:09:32
Coding entries removed.	(b) (4), (b) (6)	16 Mar 2021 19:08:59
Signature has been broken.		16 Mar 2021 19:08:59
User entered 'OSTEOARTHRITIS - BOTH KNEES,left shoulder' reason for change: Data Entry Error		16 Mar 2021 19:08:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:21:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:21:17
Data point term sent to Coder	System	07 Aug 2020 16:19:29
User entered 'Osteoarthritis - Both knees'	(b) (4), (b) (6)	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'Jan 2013'	System	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '2013'	System	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:19:27

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User coded data point as SOC: Vascular disorders, HLG: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 23:05:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 23:05:57
Data point term sent to Coder	System	16 Mar 2021 19:06:31
Coding entries removed.	(b) (4), (b) (6)	16 Mar 2021 19:05:48
Signature has been broken.		16 Mar 2021 19:05:48
User entered 'HEART MURMUR (aortic stenosis)' reason for change: Data Entry Error		16 Mar 2021 19:05:48
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:21:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 16:21:19
Data point term sent to Coder	System	07 Aug 2020 16:20:30
User entered 'Heart Murmur'	(b) (4), (b) (6)	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'Jan 2017'	System	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '2017'	System	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	07 Aug 2020 16:19:42

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '09:18'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '06 Aug 2020 09:18'	System	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '171.5' cm	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:34
DataPoint set to visible.	System	06 Aug 2020 14:50:52

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '114.0' kg	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:34
DataPoint set to visible.	System	06 Aug 2020 14:50:52

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
Amendment Manager: User entered '38.75936'	System	16 Sep 2020 23:44:59
User entered '38.8'	System	07 Aug 2020 16:20:34
DataPoint set to visible.	System	06 Aug 2020 14:50:52

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'kg/m2'	System	07 Aug 2020 16:20:34
DataPoint set to visible.	System	06 Aug 2020 14:50:52

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 16:48:14
User entered '36.5' C	(b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:48:14
User entered 'Oral (Oral)'		07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Aug 2020 16:48:14
User entered '68'	(b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'bpm'	System	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:48:14
User entered '14'		07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'breaths/min'	System	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:48:14
User entered '112'	(b) (4), (b) (6)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'mmHg'	System	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:48:14
User entered '74'	(b) (4)	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'mmHg'	System	07 Aug 2020 16:20:34

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45

US3412151

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45

US3412151

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:20:41

US3412151

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
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).	System	03 Sep 2020 11:45:18
User entered '06 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 16:20:41

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Lives with essential worker'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '1'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:15

US3412151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:23

US3412151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:23

US3412151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:23

US3412151

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'VISIT1'	System	06 Aug 2020 14:51:23

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 14:14:39

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:26:15
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:26:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 14:14:39
User entered '184925' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 14:14:39

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 14:14:39

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:43

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:43

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:43

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:43

US3412151

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:51:43

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Pre-Dose (PREDOSE)'		07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 16:49:49
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '6 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:49:49
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '09:18' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:49:49
User entered empty.	(b) (4)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '6 Aug 2020 09:18'	System	21 Aug 2020 16:49:49
User entered empty.	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '36.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:49:49
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 16:49:49
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '68' reason for change: Data Entry Error	(b) (4)	21 Aug 2020 16:49:49
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'bpm'	System	21 Aug 2020 16:49:49
User entered empty.	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:49:49
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'breaths/min'	System	21 Aug 2020 16:49:49
User entered empty.	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '112' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:49:49
User entered empty.	(b) (4)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	21 Aug 2020 16:49:49
User entered empty.	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 16:49:49
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	21 Aug 2020 16:49:49
User entered empty.	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:36:43
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 16:22:10
User entered '11:06'	(b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '06 Aug 2020 11:06'	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '62'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'bpm'	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '12'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'breaths/min'	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '120'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '80'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	07 Aug 2020 16:22:10

US3412151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:35

US3412151

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:35

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '10:35'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '06 Aug 2020 10:35'	System	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'ONCE'	System	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 14:52:25

US3412151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:29

US3412151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:29

US3412151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '09:55'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:29

US3412151

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '06 Aug 2020 09:55'	System	07 Aug 2020 16:22:29

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '06 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '10:00'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '06 Aug 2020 10:00'	System	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	07 Aug 2020 16:22:40

US3412151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 16:21:20

US3412151

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'I'	System	07 Aug 2020 16:21:20

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:14:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0d7e9640-c2b3-449d-8ec5-6399648449bd' User entered 'Yes (Y)'	System	06 Aug 2020 15:15:50
	System	06 Aug 2020 15:15:50

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:15:02', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0d7e9640-c2b3-449d-8ec5-6399648449bd' User entered '97.1'	System	06 Aug 2020 15:15:50
	System	06 Aug 2020 15:15:50

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:15:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0d7e9640-c2b3-449d-8ec5-6399648449bd' User entered 'No (N)'	System	06 Aug 2020 15:15:50
	System	06 Aug 2020 15:15:50

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:15:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0d7e9640-c2b3-449d-8ec5-6399648449bd' User entered '06 Aug 2020 11:15'	System	06 Aug 2020 15:15:50
	System	06 Aug 2020 15:15:50

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 10:55'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 13:25'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:05:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8a01b65a-bd77-4b8f-936b-e193801081b8' User entered 'Yes (Y)'	System	06 Aug 2020 23:06:03
	System	06 Aug 2020 23:06:03

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:05:46', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8a01b65a-bd77-4b8f-936b-e193801081b8' User entered '96.5'	System	06 Aug 2020 23:06:03
	System	06 Aug 2020 23:06:03

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:05:52', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8a01b65a-bd77-4b8f-936b-e193801081b8' User entered 'No (N)'	System	06 Aug 2020 23:06:03
	System	06 Aug 2020 23:06:03

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:05:59', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8a01b65a-bd77-4b8f-936b-e193801081b8' User entered '06 Aug 2020 19:05'	System	06 Aug 2020 23:06:03
	System	06 Aug 2020 23:06:03

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 14:20'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 2'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:21:11', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3f6a3131-ec55-4175-99e3-1343d0573684' User entered 'Yes (Y)'	System	07 Aug 2020 23:21:39
	System	07 Aug 2020 23:21:39

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:21:23', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3f6a3131-ec55-4175-99e3-1343d0573684' User entered '97.4'	System	07 Aug 2020 23:21:39
	System	07 Aug 2020 23:21:39

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:21:28', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3f6a3131-ec55-4175-99e3-1343d0573684' User entered 'No (N)'	System	07 Aug 2020 23:21:39
	System	07 Aug 2020 23:21:39

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:21:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3f6a3131-ec55-4175-99e3-1343d0573684' User entered '07 Aug 2020 19:21'	System	07 Aug 2020 23:21:39
	System	07 Aug 2020 23:21:39

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 3'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:02:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c8834265-4414-4ed8-87d8-10b96dbd9519' User entered 'Yes (Y)'	System	08 Aug 2020 23:02:49
	System	08 Aug 2020 23:02:49

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:02:35', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c8834265-4414-4ed8-87d8-10b96dbd9519' User entered '98.0'	System	08 Aug 2020 23:02:49
	System	08 Aug 2020 23:02:49

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:02:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c8834265-4414-4ed8-87d8-10b96dbd9519'	System	08 Aug 2020 23:02:49
User entered 'No (N)'	System	08 Aug 2020 23:02:49

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:02:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c8834265-4414-4ed8-87d8-10b96dbd9519' User entered '08 Aug 2020 19:02'	System	08 Aug 2020 23:02:49
	System	08 Aug 2020 23:02:49

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 4'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:58:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e19e30bf-1136-44cc-854e-3fea6c8a07'	System	09 Aug 2020 23:58:57
User entered 'Yes (Y)'	System	09 Aug 2020 23:58:57

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:58:43', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e19e30bf-1136-44cc-854e-3fea6d6c8a07'	System	09 Aug 2020 23:58:57
User entered '98.7'	System	09 Aug 2020 23:58:57

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:58:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e19e30bf-1136-44cc-854e-3feaed6c8a07'	System	09 Aug 2020 23:58:57
User entered 'No (N)'	System	09 Aug 2020 23:58:57

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:58:55', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e19e30bf-1136-44cc-854e-3feaed6c8a07'	System	09 Aug 2020 23:58:57
User entered '09 Aug 2020 19:58'	System	09 Aug 2020 23:58:57

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 5'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:04:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '31de4785-c90e-4fd4-859c-199635f1e435' User entered 'Yes (Y)'	System	10 Aug 2020 23:04:56
	System	10 Aug 2020 23:04:56

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:04:44', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '31de4785-c90e-4fd4-859c-199635f1e435' User entered '98.5'	System	10 Aug 2020 23:04:56
	System	10 Aug 2020 23:04:56

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:04:50', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '31de4785-c90e-4fd4-859c-199635f1e435'	System	10 Aug 2020 23:04:56
User entered 'No (N)'	System	10 Aug 2020 23:04:56

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:04:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '31de4785-c90e-4fd4-859c-199635f1e435' User entered '10 Aug 2020 19:04'	System	10 Aug 2020 23:04:56
	System	10 Aug 2020 23:04:56

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 6'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:22', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'df1098b4-db80-4ef1-b1fd-0f5fa82c0d10'	System	11 Aug 2020 23:01:43
User entered 'Yes (Y)'	System	11 Aug 2020 23:01:43

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:30', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'df1098b4-db80-4ef1-b1fd-0f5fa82c0d10'	System	11 Aug 2020 23:01:43
User entered '97.9'	System	11 Aug 2020 23:01:43

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'df1098b4-db80-4ef1-b1fd-0f5fa82c0d10'	System	11 Aug 2020 23:01:43
User entered 'No (N)'	System	11 Aug 2020 23:01:43

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:38', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'df1098b4-db80-4ef1-b1fd-0f5fa82c0d10' User entered '11 Aug 2020 19:01'	System	11 Aug 2020 23:01:43
	System	11 Aug 2020 23:01:43

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 7'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:19', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3384e6f9-2cf5-48e0-a326-1936896742fd' User entered 'Yes (Y)'	System	12 Aug 2020 22:55:38
	System	12 Aug 2020 22:55:38

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3384e6f9-2cf5-48e0-a326-1936896742fd' User entered '97.9'	System	12 Aug 2020 22:55:38
	System	12 Aug 2020 22:55:38

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:32', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3384e6f9-2cf5-48e0-a326-1936896742fd' User entered 'No (N)'	System	12 Aug 2020 22:55:38
	System	12 Aug 2020 22:55:38

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:36', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3384e6f9-2cf5-48e0-a326-1936896742fd' User entered '12 Aug 2020 18:55'	System	12 Aug 2020 22:55:38
	System	12 Aug 2020 22:55:38

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:16:36', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f9738479-7122-4f43-9049-d441c8686b2c' User entered 'None (1)'	System	06 Aug 2020 15:17:03
	System	06 Aug 2020 15:17:03

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:16:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f9738479-7122-4f43-9049-d441c8686b2c' User entered 'No (N)'	System	06 Aug 2020 15:17:03
	System	06 Aug 2020 15:17:03

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:16:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f9738479-7122-4f43-9049-d441c8686b2c' User entered 'No (N)'	System	06 Aug 2020 15:17:03
	System	06 Aug 2020 15:17:03

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:16:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f9738479-7122-4f43-9049-d441c8686b2c'	System	06 Aug 2020 15:17:03
User entered 'None (1)'	System	06 Aug 2020 15:17:03

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:16:59', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f9738479-7122-4f43-9049-d441c8686b2c' User entered '06 Aug 2020 11:16'	System	06 Aug 2020 15:17:03
	System	06 Aug 2020 15:17:03

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 10:55'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 13:25'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:11', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2cd4bb87-9007-4544-b373-61d04b46028a'	System	06 Aug 2020 23:06:32
User entered 'None (1)'	System	06 Aug 2020 23:06:32

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2cd4bb87-9007-4544-b373-61d04b46028a'	System	06 Aug 2020 23:06:32
User entered 'No (N)'	System	06 Aug 2020 23:06:32

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:19', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2cd4bb87-9007-4544-b373-61d04b46028a' User entered 'No (N)'	System	06 Aug 2020 23:06:32
	System	06 Aug 2020 23:06:32

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:23', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2cd4bb87-9007-4544-b373-61d04b46028a'	System	06 Aug 2020 23:06:32
User entered 'None (1)'	System	06 Aug 2020 23:06:32

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:30', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2cd4bb87-9007-4544-b373-61d04b46028a' User entered '06 Aug 2020 19:06'	System	06 Aug 2020 23:06:32
	System	06 Aug 2020 23:06:32

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 14:20'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 2'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:21:50', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '113e6145-1715-4457-b288-1709b7394901'	System	07 Aug 2020 23:22:15
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 23:22:15

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:21:58', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '113e6145-1715-4457-b288-1709b7394901' User entered 'No (N)'	System	07 Aug 2020 23:22:15
	System	07 Aug 2020 23:22:15

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:02', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '113e6145-1715-4457-b288-1709b7394901'	System	07 Aug 2020 23:22:15
User entered 'No (N)'	System	07 Aug 2020 23:22:15

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:07', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '113e6145-1715-4457-b288-1709b7394901'	System	07 Aug 2020 23:22:15
User entered 'None (1)'	System	07 Aug 2020 23:22:15

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:13', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '113e6145-1715-4457-b288-1709b7394901' User entered '07 Aug 2020 19:22'	System	07 Aug 2020 23:22:15
	System	07 Aug 2020 23:22:15

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 3'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:02:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '326a1448-e809-4570-a9ed-bc536e32dc36'	System	08 Aug 2020 23:03:12
User entered 'None (1)'	System	08 Aug 2020 23:03:12

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:02:57', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '326a1448-e809-4570-a9ed-bc536e32dc36' User entered 'No (N)'	System	08 Aug 2020 23:03:12
	System	08 Aug 2020 23:03:12

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '326a1448-e809-4570-a9ed-bc536e32dc36' User entered 'No (N)'	System	08 Aug 2020 23:03:12
	System	08 Aug 2020 23:03:12

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '326a1448-e809-4570-a9ed-bc536e32dc36' User entered 'None (1)'	System	08 Aug 2020 23:03:12
	System	08 Aug 2020 23:03:12

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '326a1448-e809-4570-a9ed-bc536e32dc36' User entered '08 Aug 2020 19:03'	System	08 Aug 2020 23:03:12
	System	08 Aug 2020 23:03:12

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 4'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '298d8139-6878-4e62-be11-eb758c207f0d'	System	09 Aug 2020 23:59:19
User entered 'None (1)'	System	09 Aug 2020 23:59:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:04', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '298d8139-6878-4e62-be11-eb758c207f0d' User entered 'No (N)'	System	09 Aug 2020 23:59:19
	System	09 Aug 2020 23:59:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '298d8139-6878-4e62-be11-eb758c207f0d' User entered 'No (N)'	System	09 Aug 2020 23:59:19
	System	09 Aug 2020 23:59:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:13', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '298d8139-6878-4e62-be11-eb758c207f0d' User entered 'None (1)'	System	09 Aug 2020 23:59:19
	System	09 Aug 2020 23:59:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '298d8139-6878-4e62-be11-eb758c207f0d' User entered '09 Aug 2020 19:59'	System	09 Aug 2020 23:59:19
	System	09 Aug 2020 23:59:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 5'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:04:59', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f4c6360f-34b5-470e-9600-3b06793bbc0a' User entered 'None (1)'	System	10 Aug 2020 23:05:19
	System	10 Aug 2020 23:05:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:03', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f4c6360f-34b5-470e-9600-3b06793bbc0a' User entered 'No (N)'	System	10 Aug 2020 23:05:19
	System	10 Aug 2020 23:05:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:06', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f4c6360f-34b5-470e-9600-3b06793bbc0a' User entered 'No (N)'	System	10 Aug 2020 23:05:19
	System	10 Aug 2020 23:05:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f4c6360f-34b5-470e-9600-3b06793bbc0a' User entered 'None (1)'	System	10 Aug 2020 23:05:19
	System	10 Aug 2020 23:05:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:17', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f4c6360f-34b5-470e-9600-3b06793bbc0a' User entered '10 Aug 2020 19:05'	System	10 Aug 2020 23:05:19
	System	10 Aug 2020 23:05:19

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 6'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:44', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '021a09cc-6fe2-4b27-b713-c7c979391da4'	System	11 Aug 2020 23:02:02
User entered 'None (1)'	System	11 Aug 2020 23:02:02

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:47', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '021a09cc-6fe2-4b27-b713-c7c979391da4' User entered 'No (N)'	System	11 Aug 2020 23:02:02
	System	11 Aug 2020 23:02:02

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:50', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '021a09cc-6fe2-4b27-b713-c7c979391da4' User entered 'No (N)'	System	11 Aug 2020 23:02:02
	System	11 Aug 2020 23:02:02

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '021a09cc-6fe2-4b27-b713-c7c979391da4'	System	11 Aug 2020 23:02:02
User entered 'None (1)'	System	11 Aug 2020 23:02:02

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:01:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '021a09cc-6fe2-4b27-b713-c7c979391da4' User entered '11 Aug 2020 19:01'	System	11 Aug 2020 23:02:02
	System	11 Aug 2020 23:02:02

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 7'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dce16a3-2e5e-4d58-9a36-c7dc89d6ea26'	System	12 Aug 2020 22:56:05
User entered 'None (1)'	System	12 Aug 2020 22:56:05

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dce16a3-2e5e-4d58-9a36-c7dc89d6ea26' User entered 'No (N)'	System	12 Aug 2020 22:56:05
	System	12 Aug 2020 22:56:05

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dce16a3-2e5e-4d58-9a36-c7dc89d6ea26'	System	12 Aug 2020 22:56:05
User entered 'No (N)'	System	12 Aug 2020 22:56:05

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:55:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dce16a3-2e5e-4d58-9a36-c7dc89d6ea26'	System	12 Aug 2020 22:56:05
User entered 'None (1)'	System	12 Aug 2020 22:56:05

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dce16a3-2e5e-4d58-9a36-c7dc89d6ea26' User entered '12 Aug 2020 18:56'	System	12 Aug 2020 22:56:05
	System	12 Aug 2020 22:56:05

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:12', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered 'None (0)'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered 'None (0)'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered 'None (0)'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:22', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered 'None (0)'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered 'None (0)'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:29', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered 'None (0)'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:44', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145'	System	06 Aug 2020 15:17:54
User entered 'No (N)'	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T11:17:52', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f0385ce0-742a-4f4e-b6dd-cb97a6c37145' User entered '06 Aug 2020 11:17'	System	06 Aug 2020 15:17:54
	System	06 Aug 2020 15:17:54

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 10:55'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 13:25'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered 'None (0)'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:06:59', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered 'None (0)'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:07:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered 'None (0)'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:07:16', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered 'None (0)'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:07:19', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered 'None (0)'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:07:22', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered 'None (0)'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:07:28', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2'	System	06 Aug 2020 23:07:34
User entered 'No (N)'	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-06T19:07:33', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '07db0dbe-f209-4817-98aa-e0aceff823a2' User entered '06 Aug 2020 19:07'	System	06 Aug 2020 23:07:34
	System	06 Aug 2020 23:07:34

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Aug 2020 14:20'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 2'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:21', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefba22-a85e-4978-becd-44367d0090c5' User entered 'None (0)'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefb22-a85e-4978-becd-44367d0090c5'	System	07 Aug 2020 23:23:10
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefba22-a85e-4978-becd-44367d0090c5' User entered 'None (0)'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:51', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefb22-a85e-4978-becd-44367d0090c5' User entered 'None (0)'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefba22-a85e-4978-becd-44367d0090c5' User entered 'None (0)'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:22:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefa22-a85e-4978-becd-44367d0090c5' User entered 'None (0)'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:23:03', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefba22-a85e-4978-becd-44367d0090c5' User entered 'No (N)'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-07T19:23:09', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6cefa22-a85e-4978-becd-44367d0090c5' User entered '07 Aug 2020 19:23'	System	07 Aug 2020 23:23:10
	System	07 Aug 2020 23:23:10

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 3'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'None (0)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:21', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'None (0)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'None (0)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:31', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'None (0)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'None (0)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:36', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'None (0)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered 'No (N)'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-08T19:03:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0bc05908-eb55-4d8c-8041-b9a2ec7273e8' User entered '08 Aug 2020 19:03'	System	08 Aug 2020 23:03:48
	System	08 Aug 2020 23:03:48

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 4'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'None (0)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:40', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'None (0)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'None (0)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:44', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'None (0)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'None (0)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T19:59:49', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'None (0)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T20:00:03', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered 'No (N)'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-09T20:00:13', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '58a3bd30-abe4-4543-abda-33490f05190e' User entered '09 Aug 2020 20:00'	System	10 Aug 2020 00:00:16
	System	10 Aug 2020 00:00:16

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 5'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:29', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb' User entered 'None (0)'	System	10 Aug 2020 23:06:08
	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb'	System	10 Aug 2020 23:06:08
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:40', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb' User entered 'None (0)'	System	10 Aug 2020 23:06:08
	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:50', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb' User entered 'None (0)'	System	10 Aug 2020 23:06:08
	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb' User entered 'None (0)'	System	10 Aug 2020 23:06:08
	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:05:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb' User entered 'None (0)'	System	10 Aug 2020 23:06:08
	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:06:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb'	System	10 Aug 2020 23:06:08
User entered 'No (N)'	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-10T19:06:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '749f63b0-8c06-4efa-9c48-e0985598f6bb' User entered '10 Aug 2020 19:06'	System	10 Aug 2020 23:06:08
	System	10 Aug 2020 23:06:08

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 6'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:24', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52'	System	11 Aug 2020 23:03:01
User entered 'None (0)'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:28', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52'	System	11 Aug 2020 23:03:01
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:31', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52' User entered 'None (0)'	System	11 Aug 2020 23:03:01
	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:43', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52' User entered 'None (0)'	System	11 Aug 2020 23:03:01
	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:46', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52'	System	11 Aug 2020 23:03:01
User entered 'None (0)'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52'	System	11 Aug 2020 23:03:01
User entered 'None (0)'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:55', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52'	System	11 Aug 2020 23:03:01
User entered 'No (N)'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-11T19:02:58', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c2102abd-7fb5-4ec1-bfc2-d8c70e8abd52' User entered '11 Aug 2020 19:02'	System	11 Aug 2020 23:03:01
	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 7'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:09', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'None (0)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'None (0)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:17', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'None (0)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:22', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'None (0)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:24', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'None (0)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'None (0)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:30', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered 'No (N)'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-12T18:56:33', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5f7921bd-5cd2-489a-a729-44913fed7190' User entered '12 Aug 2020 18:56'	System	12 Aug 2020 22:56:35
	System	12 Aug 2020 22:56:35

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	11 Aug 2020 23:03:01
User entered 'Day 8'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-13T19:21:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e633d712-2a4f-4fed-aa90-4606bf0d7d7a'	System	13 Aug 2020 23:21:44
User entered 'No (N)'	System	13 Aug 2020 23:21:44

US3412151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-08-13T19:21:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e633d712-2a4f-4fed-aa90-4606bf0d7d7a' User entered '13 Aug 2020 19:21'	System	13 Aug 2020 23:21:44
	System	13 Aug 2020 23:21:44

US3412151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:03:01

US3412151

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:03:01

US3412151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:05:14

US3412151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:05:14

US3412151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:05:14

US3412151

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:05:14

US3412151

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 20:05:29

US3412151

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'I'	System	13 Aug 2020 20:05:29

US3412151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:28

US3412151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:28

US3412151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:28

US3412151

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:28

US3412151

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:40:34

US3412151

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'I'	System	20 Aug 2020 19:40:34

US3412151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 21:10:38

US3412151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 21:10:38

US3412151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 21:10:38

US3412151

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 21:10:38

US3412151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 21:10:47

US3412151

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'I'	System	27 Aug 2020 21:10:47

US3412151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:18

US3412151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:18

US3412151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:18

US3412151

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'VISIT2'	System	03 Sep 2020 11:45:18

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '07:15'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '03 Sep 2020 07:15'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '36.7' C	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '78'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'bpm'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '16'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'breaths/min'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '114'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '78'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '08:36'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '03 Sep 2020 08:36'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '97.6' F	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '64'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'bpm'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '14'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'breaths/min'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '114'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '76'	Jacob sekinger (b) (4)	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'mmHg'	System	22 Sep 2020 20:23:51

US3412151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:26

US3412151

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:26

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '08:03'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '03 Sep 2020 08:03'	System	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'ONCE'	System	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 12:07:22

US3412151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:48

US3412151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:48

US3412151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '07:37'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:45:48

US3412151

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '03 Sep 2020 07:37'	System	03 Sep 2020 11:45:48

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '07:39'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '03 Sep 2020 07:39'	System	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	03 Sep 2020 11:46:00

US3412151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 11:46:04

US3412151

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '1'	System	03 Sep 2020 11:46:04

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:43:04', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e9379f68-3edf-45f1-9842-845bd6f25725'	System	03 Sep 2020 12:43:27
User entered 'Yes (Y)'	System	03 Sep 2020 12:43:27

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:43:14', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e9379f68-3edf-45f1-9842-845bd6f25725'	System	03 Sep 2020 12:43:27
User entered '97.6'	System	03 Sep 2020 12:43:27

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:43:19', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e9379f68-3edf-45f1-9842-845bd6f25725'	System	03 Sep 2020 12:43:27
User entered 'No (N)'	System	03 Sep 2020 12:43:27

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:43:24', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e9379f68-3edf-45f1-9842-845bd6f25725'	System	03 Sep 2020 12:43:27
User entered '03 Sep 2020 08:43'	System	03 Sep 2020 12:43:27

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 08:23'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 10:53'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'cb67a9f3-9120-4c0d-bad8-622cc640f4a8' User entered 'Yes (Y)'	System	03 Sep 2020 22:53:20
	System	03 Sep 2020 22:53:20

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:06', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'cb67a9f3-9120-4c0d-bad8-622cc640f4a8' User entered '98.1'	System	03 Sep 2020 22:53:20
	System	03 Sep 2020 22:53:20

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:11', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'cb67a9f3-9120-4c0d-bad8-622cc640f4a8'	System	03 Sep 2020 22:53:20
User entered 'No (N)'	System	03 Sep 2020 22:53:20

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:17', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'cb67a9f3-9120-4c0d-bad8-622cc640f4a8'	System	03 Sep 2020 22:53:20
User entered '03 Sep 2020 18:53'	System	03 Sep 2020 22:53:20

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 11:48'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 2'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:05:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c0f761ae-dba5-4d57-b3e9-ea112588615f' User entered 'Yes (Y)'	System	04 Sep 2020 22:05:58
	System	04 Sep 2020 22:05:58

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:05:47', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c0f761ae-dba5-4d57-b3e9-ea112588615f' User entered '97.5'	System	04 Sep 2020 22:05:58
	System	04 Sep 2020 22:05:58

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:05:51', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c0f761ae-dba5-4d57-b3e9-ea112588615f' User entered 'No (N)'	System	04 Sep 2020 22:05:58
	System	04 Sep 2020 22:05:58

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:05:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c0f761ae-dba5-4d57-b3e9-ea112588615f' User entered '04 Sep 2020 18:05'	System	04 Sep 2020 22:05:58
	System	04 Sep 2020 22:05:58

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 3'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:22:52', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8ef699aa-e3e4-4a05-abab-45c5e61de0f2'	System	05 Sep 2020 23:23:09
User entered 'Yes (Y)'	System	05 Sep 2020 23:23:09

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:22:58', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8ef699aa-e3e4-4a05-abab-45c5e61de0f2' User entered '98.5'	System	05 Sep 2020 23:23:09
	System	05 Sep 2020 23:23:09

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8ef699aa-e3e4-4a05-abab-45c5e61de0f2'	System	05 Sep 2020 23:23:09
User entered 'No (N)'	System	05 Sep 2020 23:23:09

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '8ef699aa-e3e4-4a05-abab-45c5e61de0f2'	System	05 Sep 2020 23:23:09
User entered '05 Sep 2020 19:23'	System	05 Sep 2020 23:23:09

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 4'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:41:33', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2bda86d5-10f6-426f-8f96-79dbfeeb34e6' User entered 'Yes (Y)'	System	06 Sep 2020 22:42:17
	System	06 Sep 2020 22:42:17

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:41:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2bda86d5-10f6-426f-8f96-79dbfeeb34e6' User entered '97.7'	System	06 Sep 2020 22:42:17
	System	06 Sep 2020 22:42:17

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:41:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2bda86d5-10f6-426f-8f96-79dbfeeb34e6' User entered 'Yes (Y)'	System	06 Sep 2020 22:42:17
	System	06 Sep 2020 22:42:17

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACTED' (Site from System).	(b) (4)	14 Oct 2020 10:22:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios (b) (4)	02 Oct 2020 17:18:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:07', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2bda86d5-10f6-426f-8f96-79dbfeeb34e6'	System	06 Sep 2020 22:42:17
User entered '1'	System	06 Sep 2020 22:42:17

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:07', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2bda86d5-10f6-426f-8f96-79dbfeeb34e6' User entered '0'	System	06 Sep 2020 22:42:17
	System	06 Sep 2020 22:42:17

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:16', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2bda86d5-10f6-426f-8f96-79dbfeeb34e6' User entered '06 Sep 2020 18:42'	System	06 Sep 2020 22:42:17
	System	06 Sep 2020 22:42:17

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 5'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:06', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89f11927-806a-424a-a035-06c967ef2307'	System	07 Sep 2020 22:35:24
User entered 'Yes (Y)'	System	07 Sep 2020 22:35:24

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:11', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89f11927-806a-424a-a035-06c967ef2307' User entered '98.0'	System	07 Sep 2020 22:35:24
	System	07 Sep 2020 22:35:24

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89f11927-806a-424a-a035-06c967ef2307'	System	07 Sep 2020 22:35:24
User entered 'No (N)'	System	07 Sep 2020 22:35:24

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:21', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89f11927-806a-424a-a035-06c967ef2307'	System	07 Sep 2020 22:35:24
User entered '07 Sep 2020 18:35'	System	07 Sep 2020 22:35:24

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 6'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:20:33', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2351d0a3-a08f-4dfd-9a8f-6a15e314b5cd' User entered 'Yes (Y)'	System	08 Sep 2020 22:20:50
	System	08 Sep 2020 22:20:50

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:20:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2351d0a3-a08f-4dfd-9a8f-6a15e314b5cd' User entered '96.9'	System	08 Sep 2020 22:20:50
	System	08 Sep 2020 22:20:50

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:20:46', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2351d0a3-a08f-4dfd-9a8f-6a15e314b5cd' User entered 'No (N)'	System	08 Sep 2020 22:20:50
	System	08 Sep 2020 22:20:50

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:20:49', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2351d0a3-a08f-4dfd-9a8f-6a15e314b5cd' User entered '08 Sep 2020 18:20'	System	08 Sep 2020 22:20:50
	System	08 Sep 2020 22:20:50

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 7'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:57:21', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92e2ed40-da32-4f0f-bcc6-c3f826ea6296' User entered 'Yes (Y)'	System	09 Sep 2020 22:57:47
	System	09 Sep 2020 22:57:47

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:57:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92e2ed40-da32-4f0f-bcc6-c3f826ea6296' User entered '98.1'	System	09 Sep 2020 22:57:47
	System	09 Sep 2020 22:57:47

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:57:29', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92e2ed40-da32-4f0f-bcc6-c3f826ea6296' User entered 'No (N)'	System	09 Sep 2020 22:57:47
	System	09 Sep 2020 22:57:47

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:57:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92e2ed40-da32-4f0f-bcc6-c3f826ea6296' User entered '09 Sep 2020 18:57'	System	09 Sep 2020 22:57:47
	System	09 Sep 2020 22:57:47

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:43:57', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '40c58260-8e2e-4cde-8de9-7b44e1188ffb'	System	03 Sep 2020 12:44:21
User entered 'None (1)'	System	03 Sep 2020 12:44:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '40c58260-8e2e-4cde-8de9-7b44e1188ffb' User entered 'No (N)'	System	03 Sep 2020 12:44:21
	System	03 Sep 2020 12:44:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:08', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '40c58260-8e2e-4cde-8de9-7b44e1188ffb' User entered 'No (N)'	System	03 Sep 2020 12:44:21
	System	03 Sep 2020 12:44:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:14', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '40c58260-8e2e-4cde-8de9-7b44e1188ffb'	System	03 Sep 2020 12:44:21
User entered 'None (1)'	System	03 Sep 2020 12:44:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '40c58260-8e2e-4cde-8de9-7b44e1188ffb' User entered '03 Sep 2020 08:44'	System	03 Sep 2020 12:44:21
	System	03 Sep 2020 12:44:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 08:23'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 10:53'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:22', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2d2dc38b-4979-4f92-a0f3-3b23ab139778'	System	03 Sep 2020 22:53:39
User entered 'None (1)'	System	03 Sep 2020 22:53:39

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2d2dc38b-4979-4f92-a0f3-3b23ab139778' User entered 'No (N)'	System	03 Sep 2020 22:53:39
	System	03 Sep 2020 22:53:39

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:28', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2d2dc38b-4979-4f92-a0f3-3b23ab139778' User entered 'No (N)'	System	03 Sep 2020 22:53:39
	System	03 Sep 2020 22:53:39

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:31', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2d2dc38b-4979-4f92-a0f3-3b23ab139778'	System	03 Sep 2020 22:53:39
User entered 'None (1)'	System	03 Sep 2020 22:53:39

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2d2dc38b-4979-4f92-a0f3-3b23ab139778' User entered '03 Sep 2020 18:53'	System	03 Sep 2020 22:53:39
	System	03 Sep 2020 22:53:39

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 11:48'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 2'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3b0ffa75-bfd2-4ede-84e7-b076f6c83f53'	System	04 Sep 2020 22:06:21
User entered 'None (1)'	System	04 Sep 2020 22:06:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3b0ffa75-bfd2-4ede-84e7-b076f6c83f53'	System	04 Sep 2020 22:06:21
User entered 'No (N)'	System	04 Sep 2020 22:06:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3b0ffa75-bfd2-4ede-84e7-b076f6c83f53'	System	04 Sep 2020 22:06:21
User entered 'No (N)'	System	04 Sep 2020 22:06:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3b0ffa75-bfd2-4ede-84e7-b076f6c83f53'	System	04 Sep 2020 22:06:21
User entered 'None (1)'	System	04 Sep 2020 22:06:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:19', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3b0ffa75-bfd2-4ede-84e7-b076f6c83f53'	System	04 Sep 2020 22:06:21
User entered '04 Sep 2020 18:06'	System	04 Sep 2020 22:06:21

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 3'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:12', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bd832119-4200-4602-b187-e2a82ac943e6'	System	05 Sep 2020 23:23:36
User entered 'None (1)'	System	05 Sep 2020 23:23:36

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:16', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bd832119-4200-4602-b187-e2a82ac943e6' User entered 'No (N)'	System	05 Sep 2020 23:23:36
	System	05 Sep 2020 23:23:36

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:20', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bd832119-4200-4602-b187-e2a82ac943e6' User entered 'No (N)'	System	05 Sep 2020 23:23:36
	System	05 Sep 2020 23:23:36

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:31', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bd832119-4200-4602-b187-e2a82ac943e6'	System	05 Sep 2020 23:23:36
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:23:36

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bd832119-4200-4602-b187-e2a82ac943e6' User entered '05 Sep 2020 19:23'	System	05 Sep 2020 23:23:36
	System	05 Sep 2020 23:23:36

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 4'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:36', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '9bdd47e8-bae1-4e23-be11-8f18235160eb' User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 22:43:03
	System	06 Sep 2020 22:43:03

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:40', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '9bdd47e8-bae1-4e23-be11-8f18235160eb' User entered 'No (N)'	System	06 Sep 2020 22:43:03
	System	06 Sep 2020 22:43:03

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '9bdd47e8-bae1-4e23-be11-8f18235160eb' User entered 'No (N)'	System	06 Sep 2020 22:43:03
	System	06 Sep 2020 22:43:03

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:42:57', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '9bdd47e8-bae1-4e23-be11-8f18235160eb' User entered 'None (1)'	System	06 Sep 2020 22:43:03
	System	06 Sep 2020 22:43:03

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '9bdd47e8-bae1-4e23-be11-8f18235160eb' User entered '06 Sep 2020 18:43'	System	06 Sep 2020 22:43:03
	System	06 Sep 2020 22:43:03

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 5'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:27', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '54845ab0-d31d-433d-877b-1479ab160aaf'	System	07 Sep 2020 22:35:46
User entered 'None (1)'	System	07 Sep 2020 22:35:46

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:31', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '54845ab0-d31d-433d-877b-1479ab160aaf' User entered 'No (N)'	System	07 Sep 2020 22:35:46
	System	07 Sep 2020 22:35:46

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:35', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '54845ab0-d31d-433d-877b-1479ab160aaf' User entered 'No (N)'	System	07 Sep 2020 22:35:46
	System	07 Sep 2020 22:35:46

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:38', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '54845ab0-d31d-433d-877b-1479ab160aaf' User entered 'None (1)'	System	07 Sep 2020 22:35:46
	System	07 Sep 2020 22:35:46

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:35:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '54845ab0-d31d-433d-877b-1479ab160aaf' User entered '07 Sep 2020 18:35'	System	07 Sep 2020 22:35:46
	System	07 Sep 2020 22:35:46

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 6'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:20:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0c9b4654-5079-4cbd-977d-5e2f84157b08'	System	08 Sep 2020 22:21:14
User entered 'None (1)'	System	08 Sep 2020 22:21:14

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:20:58', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0c9b4654-5079-4cbd-977d-5e2f84157b08' User entered 'No (N)'	System	08 Sep 2020 22:21:14
	System	08 Sep 2020 22:21:14

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0c9b4654-5079-4cbd-977d-5e2f84157b08'	System	08 Sep 2020 22:21:14
User entered 'No (N)'	System	08 Sep 2020 22:21:14

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:08', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0c9b4654-5079-4cbd-977d-5e2f84157b08'	System	08 Sep 2020 22:21:14
User entered 'None (1)'	System	08 Sep 2020 22:21:14

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:11', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '0c9b4654-5079-4cbd-977d-5e2f84157b08'	System	08 Sep 2020 22:21:14
User entered '08 Sep 2020 18:21'	System	08 Sep 2020 22:21:14

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 7'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:57:51', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3a6e6179-b26d-4a75-be46-30098ad286af' User entered 'None (1)'	System	09 Sep 2020 22:58:12
	System	09 Sep 2020 22:58:12

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:57:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3a6e6179-b26d-4a75-be46-30098ad286af' User entered 'No (N)'	System	09 Sep 2020 22:58:12
	System	09 Sep 2020 22:58:12

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:58:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3a6e6179-b26d-4a75-be46-30098ad286af' User entered 'No (N)'	System	09 Sep 2020 22:58:12
	System	09 Sep 2020 22:58:12

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:58:07', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3a6e6179-b26d-4a75-be46-30098ad286af' User entered 'None (1)'	System	09 Sep 2020 22:58:12
	System	09 Sep 2020 22:58:12

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:58:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '3a6e6179-b26d-4a75-be46-30098ad286af' User entered '09 Sep 2020 18:58'	System	09 Sep 2020 22:58:12
	System	09 Sep 2020 22:58:12

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'None (0)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'None (0)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:40', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'None (0)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'None (0)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'None (0)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:51', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'None (0)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered 'No (N)'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T08:44:59', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '25ebf54b-77e5-4ebf-91a5-a499f08343e4' User entered '03 Sep 2020 08:44'	System	03 Sep 2020 12:45:02
	System	03 Sep 2020 12:45:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 08:23'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 10:53'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'None (0)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:49', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'None (0)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'None (0)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:56', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'None (0)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:53:59', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'None (0)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:54:03', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'None (0)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:54:08', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered 'No (N)'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-03T18:54:16', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b70c74b7-accb-4321-87ca-c00b9c6a3c4b' User entered '03 Sep 2020 18:54'	System	03 Sep 2020 22:54:18
	System	03 Sep 2020 22:54:18

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '03 Sep 2020 11:48'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 2'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888' User entered 'None (0)'	System	04 Sep 2020 22:07:10
	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:40', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888'	System	04 Sep 2020 22:07:10
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:43', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888' User entered 'None (0)'	System	04 Sep 2020 22:07:10
	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:47', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888' User entered 'None (0)'	System	04 Sep 2020 22:07:10
	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:50', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888' User entered 'None (0)'	System	04 Sep 2020 22:07:10
	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:06:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888' User entered 'None (0)'	System	04 Sep 2020 22:07:10
	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:07:02', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888'	System	04 Sep 2020 22:07:10
User entered 'No (N)'	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-04T18:07:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '84358856-9c89-4f21-8035-799726cff888' User entered '04 Sep 2020 18:07'	System	04 Sep 2020 22:07:10
	System	04 Sep 2020 22:07:10

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 3'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered 'None (0)'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered 'None (0)'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:45', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered 'None (0)'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:47', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered 'None (0)'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:51', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered 'None (0)'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:55', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered 'None (0)'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:23:58', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc'	System	05 Sep 2020 23:24:03
User entered 'No (N)'	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-05T19:24:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'b71dd666-47c8-4c50-8ab6-df1cdad4b0bc' User entered '05 Sep 2020 19:24'	System	05 Sep 2020 23:24:03
	System	05 Sep 2020 23:24:03

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 4'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:06', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527'	System	06 Sep 2020 22:43:34
User entered 'None (0)'	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:09', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527'	System	06 Sep 2020 22:43:34
User entered 'None (0)'	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:12', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527'	System	06 Sep 2020 22:43:34
User entered 'None (0)'	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527' User entered 'None (0)'	System	06 Sep 2020 22:43:34
	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527'	System	06 Sep 2020 22:43:34
User entered 'None (0)'	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:21', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527' User entered 'None (0)'	System	06 Sep 2020 22:43:34
	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527'	System	06 Sep 2020 22:43:34
User entered 'No (N)'	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-06T18:43:30', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'aa9d8fcd-a0a0-4c9a-b68b-93cf75a93527'	System	06 Sep 2020 22:43:34
User entered '06 Sep 2020 18:43'	System	06 Sep 2020 22:43:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 5'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:13', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'None (0)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:27', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'None (0)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:30', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'None (0)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:32', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'None (0)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:34', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'None (0)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'None (0)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:36:57', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered 'No (N)'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-07T18:37:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '6779d56d-f911-4afe-98ca-66e227d87e16' User entered '07 Sep 2020 18:37'	System	07 Sep 2020 22:37:02
	System	07 Sep 2020 22:37:02

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 6'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered 'None (0)'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered 'None (0)'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:20', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered 'None (0)'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:22', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered 'None (0)'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:24', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered 'None (0)'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered 'None (0)'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:29', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3'	System	08 Sep 2020 22:21:34
User entered 'No (N)'	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-08T18:21:32', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '92d7c1ea-c6c0-447b-9422-c1407f6ca4c3' User entered '08 Sep 2020 18:21'	System	08 Sep 2020 22:21:34
	System	08 Sep 2020 22:21:34

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	03 Sep 2020 12:07:22
User entered 'Day 7'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:58:57', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'None (0)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'None (0)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:03', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'None (0)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:17', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'None (0)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:20', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'None (0)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:23', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'None (0)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:35', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered 'No (N)'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-09-09T18:59:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '849a37c9-6f35-48a7-9d61-9a97af722c4d' User entered '09 Sep 2020 18:59'	System	09 Sep 2020 22:59:42
	System	09 Sep 2020 22:59:42

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 12:07:22

US3412151

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 12:07:22

US3412151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Sep 2020 19:05:52

US3412151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered '10 Sep 2020'	Mason Urban (b) (4)	10 Sep 2020 19:05:52

US3412151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	10 Sep 2020 19:05:52

US3412151

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered empty.	Mason Urban (b) (4)	10 Sep 2020 19:05:52

US3412151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:51:49
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Sep 2020 19:05:59

US3412151

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '1'	System	10 Sep 2020 19:05:59

US3412151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 14:43:04

US3412151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '17 Sep 2020'	Mason Urban (b) (4)	17 Sep 2020 14:43:04

US3412151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Sep 2020 14:43:04

US3412151

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	Mason Urban (b) (4)	17 Sep 2020 14:43:04

US3412151

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 14:43:17

US3412151

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '1'	System	17 Sep 2020 14:43:17

US3412151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 14:38:04

US3412151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '25 Sep 2020'	Mason Urban (b) (4)	25 Sep 2020 14:38:04

US3412151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Sep 2020 14:38:04

US3412151

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	Mason Urban (b) (4)	25 Sep 2020 14:38:04

US3412151

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 14:38:09

US3412151

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '1'	System	25 Sep 2020 14:38:09

US3412151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:43

US3412151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:43

US3412151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:43

US3412151

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered 'VISIT3'	System	01 Oct 2020 12:37:43

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered empty.	System	01 Oct 2020 12:37:59

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00

US3412151

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00

US3412151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Dec 2020 17:06:28
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	01 Oct 2020 12:38:07
	(b) (4), (b) (6)	

US3412151

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered empty; reason for change Data Entry Error	(b) (4)	06 Dec 2020 17:06:28
User entered '01 Oct 2020'	Melissa Fuson (b) (4)	01 Oct 2020 12:38:07
	(b) (4)	
	(b) (4), (b) (6)	

US3412151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:38:32

US3412151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:38:32

US3412151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered '07:50'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:38:32

US3412151

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '01 Oct 2020 07:50'	System	01 Oct 2020 12:38:32

US3412151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:39:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:38:42

US3412151

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '1'	System	01 Oct 2020 12:38:42

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 64'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-08T21:58:19', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1eaa1951-2eea-441a-85d8-aa627e7c5904' User entered 'No (N)'	System	09 Oct 2020 01:58:31
	System	09 Oct 2020 01:58:31

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-08T21:58:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1eaa1951-2eea-441a-85d8-aa627e7c5904'	System	09 Oct 2020 01:58:31
User entered 'No (N)'	System	09 Oct 2020 01:58:31

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-08T21:58:29', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1eaa1951-2eea-441a-85d8-aa627e7c5904' User entered '08 Oct 2020 21:58:29'	System	09 Oct 2020 01:58:31
	System	09 Oct 2020 01:58:31

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 71'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-15T16:13:12', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e7ca0ce7-5c35-4eff-bde0-19b4c01c7386'	System	15 Oct 2020 20:13:24
User entered 'No (N)'	System	15 Oct 2020 20:13:24

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-15T16:13:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e7ca0ce7-5c35-4eff-bde0-19b4c01c7386'	System	15 Oct 2020 20:13:24
User entered 'No (N)'	System	15 Oct 2020 20:13:24

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-15T16:13:18', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'e7ca0ce7-5c35-4eff-bde0-19b4c01c7386' User entered '15 Oct 2020 16:13:18'	System	15 Oct 2020 20:13:24
	System	15 Oct 2020 20:13:24

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 78'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-22T12:00:36', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dd13967-6c67-444c-a0f5-51707efeab7'	System	22 Oct 2020 16:01:13
User entered 'No (N)'	System	22 Oct 2020 16:01:13

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-22T12:00:42', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dd13967-6c67-444c-a0f5-51707efeaab7'	System	22 Oct 2020 16:01:13
User entered 'No (N)'	System	22 Oct 2020 16:01:13

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-10-22T12:00:47', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '1dd13967-6c67-444c-a0f5-51707efeaab7' User entered '22 Oct 2020 12:00:47'	System	22 Oct 2020 16:01:13
	System	22 Oct 2020 16:01:13

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 92'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-05T13:58:16', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bddeb8f8-7ae7-4bf7-836a-90c5def140dc'	System	05 Nov 2020 18:58:34
User entered 'No (N)'	System	05 Nov 2020 18:58:34

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-05T13:58:20', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bddeb8f8-7ae7-4bf7-836a-90c5def140dc'	System	05 Nov 2020 18:58:34
User entered 'No (N)'	System	05 Nov 2020 18:58:34

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-05T13:58:27', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bddeb8f8-7ae7-4bf7-836a-90c5def140dc' User entered '05 Nov 2020 13:58:27'	System	05 Nov 2020 18:58:34
	System	05 Nov 2020 18:58:34

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 99'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-12T13:01:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f266f6fa-6e6e-44d0-8918-1b3a11d1760d'	System	12 Nov 2020 19:01:50
User entered 'No (N)'	System	12 Nov 2020 19:01:50

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-12T13:01:43', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f266f6fa-6e6e-44d0-8918-1b3a11d1760d'	System	12 Nov 2020 19:01:50
User entered 'No (N)'	System	12 Nov 2020 19:01:50

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-12T13:01:48', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'f266f6fa-6e6e-44d0-8918-1b3a11d1760d' User entered '12 Nov 2020 13:01:48'	System	12 Nov 2020 19:01:50
	System	12 Nov 2020 19:01:50

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:23:50
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04
Data entry locked.	System	06 Aug 2020 14:52:25
User entered 'Day 106'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 14:52:25

US3412151

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:10:04
Data entry locked.	System	06 Aug 2020 14:52:25
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 14:52:25

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-21T08:11:07', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '7a1c18f8-f0ce-46b8-8382-08cbb0429d59'	System	21 Nov 2020 13:11:29
User entered 'No (N)'	System	21 Nov 2020 13:11:29

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-21T08:11:17', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '7a1c18f8-f0ce-46b8-8382-08cbb0429d59' User entered 'No (N)'	System	21 Nov 2020 13:11:29
	System	21 Nov 2020 13:11:29

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-21T08:11:24', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '7a1c18f8-f0ce-46b8-8382-08cbb0429d59'	System	21 Nov 2020 13:11:29
User entered '21 Nov 2020 08:11:24'	System	21 Nov 2020 13:11:29

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-28T14:49:36', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c62ee2d4-a071-4da4-8f6a-ea9c6e1efe57'	System	28 Nov 2020 19:49:56
User entered 'No (N)'	System	28 Nov 2020 19:49:56

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-28T14:49:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c62ee2d4-a071-4da4-8f6a-ea9c6e1efe57'	System	28 Nov 2020 19:49:56
User entered 'No (N)'	System	28 Nov 2020 19:49:56

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-11-28T14:49:53', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'c62ee2d4-a071-4da4-8f6a-ea9c6e1efe57'	System	28 Nov 2020 19:49:56
User entered '28 Nov 2020 14:49:53'	System	28 Nov 2020 19:49:56

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-05T08:06:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '224052ba-6465-475f-b6f5-5a08aad05351'	System	05 Dec 2020 13:06:55
User entered 'No (N)'	System	05 Dec 2020 13:06:55

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-05T08:06:46', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '224052ba-6465-475f-b6f5-5a08aad05351'	System	05 Dec 2020 13:06:55
User entered 'No (N)'	System	05 Dec 2020 13:06:55

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-05T08:06:52', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '224052ba-6465-475f-b6f5-5a08aad05351' User entered '05 Dec 2020 08:06:52'	System	05 Dec 2020 13:06:55
	System	05 Dec 2020 13:06:55

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-12T10:36:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5c7e6e92-8b88-4da7-8116-319ace078db6'	System	12 Dec 2020 15:36:12
User entered 'No (N)'	System	12 Dec 2020 15:36:12

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-12T10:36:05', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5c7e6e92-8b88-4da7-8116-319ace078db6'	System	12 Dec 2020 15:36:12
User entered 'No (N)'	System	12 Dec 2020 15:36:12

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-12T10:36:09', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '5c7e6e92-8b88-4da7-8116-319ace078db6'	System	12 Dec 2020 15:36:12
User entered '12 Dec 2020 10:36:09'	System	12 Dec 2020 15:36:12

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-19T18:05:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '4e7badb9-f46a-451b-b99c-4b85f5606802'	System	19 Dec 2020 23:05:50
User entered 'No (N)'	System	19 Dec 2020 23:05:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-19T18:05:44', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '4e7badb9-f46a-451b-b99c-4b85f5606802'	System	19 Dec 2020 23:05:50
User entered 'No (N)'	System	19 Dec 2020 23:05:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-19T18:05:47', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '4e7badb9-f46a-451b-b99c-4b85f5606802'	System	19 Dec 2020 23:05:50
User entered '19 Dec 2020 18:05:47'	System	19 Dec 2020 23:05:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-26T07:56:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'fda9d039-5fdd-402a-894b-510f8473a17a'	System	26 Dec 2020 12:56:29
User entered 'No (N)'	System	26 Dec 2020 12:56:29

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-26T07:56:23', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'fda9d039-5fdd-402a-894b-510f8473a17a'	System	26 Dec 2020 12:56:29
User entered 'No (N)'	System	26 Dec 2020 12:56:29

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2020-12-26T07:56:27', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'fda9d039-5fdd-402a-894b-510f8473a17a' User entered '26 Dec 2020 07:56:27'	System	26 Dec 2020 12:56:29
	System	26 Dec 2020 12:56:29

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-04T11:22:08', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '410b4975-e1fb-41b2-8d80-c7f87df98920'	System	04 Jan 2021 16:22:20
User entered 'No (N)'	System	04 Jan 2021 16:22:20

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-04T11:22:12', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '410b4975-e1fb-41b2-8d80-c7f87df98920'	System	04 Jan 2021 16:22:20
User entered 'No (N)'	System	04 Jan 2021 16:22:20

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-04T11:22:16', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '410b4975-e1fb-41b2-8d80-c7f87df98920'	System	04 Jan 2021 16:22:20
User entered '04 Jan 2021 11:22:16'	System	04 Jan 2021 16:22:20

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-10T10:14:33', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'acb666f6-52f4-471b-b860-699a98e651ad' User entered 'No (N)'	System	10 Jan 2021 15:14:43
	System	10 Jan 2021 15:14:43

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-10T10:14:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'acb666f6-52f4-471b-b860-699a98e651ad' User entered 'No (N)'	System	10 Jan 2021 15:14:43
	System	10 Jan 2021 15:14:43

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-10T10:14:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'acb666f6-52f4-471b-b860-699a98e651ad' User entered '10 Jan 2021 10:14:41'	System	10 Jan 2021 15:14:43
	System	10 Jan 2021 15:14:43

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-16T08:52:50', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '30862b2b-cb16-473a-8ee3-5c00050e2199'	System	16 Jan 2021 13:53:00
User entered 'No (N)'	System	16 Jan 2021 13:53:00

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-16T08:52:54', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '30862b2b-cb16-473a-8ee3-5c00050e2199'	System	16 Jan 2021 13:53:00
User entered 'No (N)'	System	16 Jan 2021 13:53:00

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-16T08:52:58', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '30862b2b-cb16-473a-8ee3-5c00050e2199'	System	16 Jan 2021 13:53:00
User entered '16 Jan 2021 08:52:58'	System	16 Jan 2021 13:53:00

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-23T20:05:04', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '33244d28-a82c-41f3-96bd-35fc8f2aca31'	System	24 Jan 2021 01:05:15
User entered 'No (N)'	System	24 Jan 2021 01:05:15

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-23T20:05:08', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '33244d28-a82c-41f3-96bd-35fc8f2aca31'	System	24 Jan 2021 01:05:15
User entered 'No (N)'	System	24 Jan 2021 01:05:15

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-01-23T20:05:12', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '33244d28-a82c-41f3-96bd-35fc8f2aca31'	System	24 Jan 2021 01:05:15
User entered '23 Jan 2021 20:05:12'	System	24 Jan 2021 01:05:15

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-01T12:00:37', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2094d81f-dcf6-4916-92aa-780d53b8a899'	System	01 Feb 2021 17:02:46
User entered 'No (N)'	System	01 Feb 2021 17:02:46

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-01T12:00:41', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2094d81f-dcf6-4916-92aa-780d53b8a899'	System	01 Feb 2021 17:02:46
User entered 'No (N)'	System	01 Feb 2021 17:02:46

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-01T12:00:44', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '2094d81f-dcf6-4916-92aa-780d53b8a899'	System	01 Feb 2021 17:02:46
User entered '01 Feb 2021 12:00:44'	System	01 Feb 2021 17:02:46

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-06T18:36:01', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'd9ceb847-f769-4995-a536-5f8018b8f9e9'	System	06 Feb 2021 23:36:17
User entered 'No (N)'	System	06 Feb 2021 23:36:17

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-06T18:36:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'd9ceb847-f769-4995-a536-5f8018b8f9e9'	System	06 Feb 2021 23:36:17
User entered 'No (N)'	System	06 Feb 2021 23:36:17

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-06T18:36:14', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'd9ceb847-f769-4995-a536-5f8018b8f9e9'	System	06 Feb 2021 23:36:17
User entered '06 Feb 2021 18:36:14'	System	06 Feb 2021 23:36:17

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-15T20:49:25', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b12f6b-099b-43ac-9ea5-49a5c2e5fb24'	System	16 Feb 2021 01:49:38
User entered 'No (N)'	System	16 Feb 2021 01:49:38

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-15T20:49:28', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b12f6b-099b-43ac-9ea5-49a5c2e5fb24'	System	16 Feb 2021 01:49:38
User entered 'No (N)'	System	16 Feb 2021 01:49:38

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-15T20:49:32', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b12f6b-099b-43ac-9ea5-49a5c2e5fb24'	System	16 Feb 2021 01:49:38
User entered '15 Feb 2021 20:49:32'	System	16 Feb 2021 01:49:38

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-22T13:48:02', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '913e78f1-f916-4c81-b436-4f55692b2187'	System	22 Feb 2021 18:48:51
User entered 'Yes (Y)'	System	22 Feb 2021 18:48:51

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-22T13:48:10', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '913e78f1-f916-4c81-b436-4f55692b2187'	System	22 Feb 2021 18:48:51
User entered 'No (N)'	System	22 Feb 2021 18:48:51

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-22T13:48:15', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '913e78f1-f916-4c81-b436-4f55692b2187'	System	22 Feb 2021 18:48:51
User entered 'No (N)'	System	22 Feb 2021 18:48:51

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-22T13:48:26', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '913e78f1-f916-4c81-b436-4f55692b2187'	System	22 Feb 2021 18:48:51
User entered 'Yes (Y)'	System	22 Feb 2021 18:48:51

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Please 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-22T13:48:33', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '913e78f1-f916-4c81-b436-4f55692b2187'	System	22 Feb 2021 18:48:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 18:48:51

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-22T13:48:39', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '913e78f1-f916-4c81-b436-4f55692b2187'	System	22 Feb 2021 18:48:51
User entered '22 Feb 2021 13:48:39'	System	22 Feb 2021 18:48:51

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-27T12:25:10-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'ab6d9cfc-e6ed-4dae-9f86-22a65cd8c0d0'	System	27 Feb 2021 17:25:20
User entered 'No (N)'	System	27 Feb 2021 17:25:20

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-27T12:25:13-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'ab6d9cfc-e6ed-4dae-9f86-22a65cd8c0d0'	System	27 Feb 2021 17:25:20
User entered 'No (N)'	System	27 Feb 2021 17:25:20

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-27T12:25:18-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'ab6d9cfc-e6ed-4dae-9f86-22a65cd8c0d0'	System	27 Feb 2021 17:25:20
User entered '27 Feb 2021 17:25:18'	System	27 Feb 2021 17:25:20

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-08T13:00:29-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bbecaf3b-f102-49e2-90e3-7fa9d8bf4942'	System	08 Mar 2021 18:00:56
User entered 'No (N)'	System	08 Mar 2021 18:00:56

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-08T13:00:33-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bbecaf3b-f102-49e2-90e3-7fa9d8bf4942'	System	08 Mar 2021 18:00:56
User entered 'No (N)'	System	08 Mar 2021 18:00:56

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-08T13:00:37-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'bbecaf3b-f102-49e2-90e3-7fa9d8bf4942'	System	08 Mar 2021 18:00:56
User entered '08 Mar 2021 13:00:37'	System	08 Mar 2021 18:00:56

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-13T07:27:49-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '844ba67c-26cb-4701-a5cd-5f65b1fd7e5d'	System	13 Mar 2021 12:28:02
User entered 'No (N)'	System	13 Mar 2021 12:28:02

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-13T07:27:55-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '844ba67c-26cb-4701-a5cd-5f65b1fd7e5d'	System	13 Mar 2021 12:28:02
User entered 'No (N)'	System	13 Mar 2021 12:28:02

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-13T07:27:59-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '844ba67c-26cb-4701-a5cd-5f65b1fd7e5d'	System	13 Mar 2021 12:28:02
User entered '13 Mar 2021 07:27:59'	System	13 Mar 2021 12:28:02

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-20T11:33:04-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89c094f3-e3d9-49f5-a87a-b848e4ab37a1'	System	20 Mar 2021 15:33:44
User entered 'Yes (Y)'	System	20 Mar 2021 15:33:44

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-20T11:33:08-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89c094f3-e3d9-49f5-a87a-b848e4ab37a1'	System	20 Mar 2021 15:33:44
User entered 'No (N)'	System	20 Mar 2021 15:33:44

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-20T11:33:14-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89c094f3-e3d9-49f5-a87a-b848e4ab37a1'	System	20 Mar 2021 15:33:44
User entered 'No (N)'	System	20 Mar 2021 15:33:44

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-20T11:33:25-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89c094f3-e3d9-49f5-a87a-b848e4ab37a1'	System	20 Mar 2021 15:33:44
User entered 'Yes (Y)'	System	20 Mar 2021 15:33:44

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Please 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-20T11:33:31-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89c094f3-e3d9-49f5-a87a-b848e4ab37a1'	System	20 Mar 2021 15:33:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Mar 2021 15:33:44

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-20T11:33:35-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '89c094f3-e3d9-49f5-a87a-b848e4ab37a1'	System	20 Mar 2021 15:33:44
User entered '20 Mar 2021 11:33:35'	System	20 Mar 2021 15:33:44

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-27T11:24:20-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b9bd22-469b-4ff3-8880-d56e5bb7f7a2'	System	27 Mar 2021 15:24:50
User entered 'Yes (Y)'	System	27 Mar 2021 15:24:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Have you been exposed to someone with 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-27T11:24:24-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b9bd22-469b-4ff3-8880-d56e5bb7f7a2'	System	27 Mar 2021 15:24:50
User entered 'No (N)'	System	27 Mar 2021 15:24:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-27T11:24:27-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b9bd22-469b-4ff3-8880-d56e5bb7f7a2'	System	27 Mar 2021 15:24:50
User entered 'No (N)'	System	27 Mar 2021 15:24:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-27T11:24:31-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b9bd22-469b-4ff3-8880-d56e5bb7f7a2'	System	27 Mar 2021 15:24:50
User entered 'Yes (Y)'	System	27 Mar 2021 15:24:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

Please 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 (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-27T11:24:34-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b9bd22-469b-4ff3-8880-d56e5bb7f7a2'	System	27 Mar 2021 15:24:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Mar 2021 15:24:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-03-27T11:24:38-04:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: '20b9bd22-469b-4ff3-8880-d56e5bb7f7a2'	System	27 Mar 2021 15:24:50
User entered '27 Mar 2021 11:24:38'	System	27 Mar 2021 15:24:50

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:10:04

US3412151

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:10:04
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:10:04

US3412151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-27T12:25:26-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'ca911583-2647-4a51-961b-a54d26b77675'	System	27 Feb 2021 17:25:41
User entered 'No (N)'	System	27 Feb 2021 17:25:41

US3412151

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:27:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (64C30283-A3B9-4020-99C7-D14CC97B1CE9)', Time: '2021-02-27T12:25:30-05:00', User OID: 'PatientReportedOutcome (US3412151)', ODM File OID: 'ca911583-2647-4a51-961b-a54d26b77675'	System	27 Feb 2021 17:25:41
User entered '27 Feb 2021 17:25:30'	System	27 Feb 2021 17:25:41

US3412151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:18
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Oct 2020 14:44:52

US3412151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:18
User entered '29 Oct 2020'	Mason Urban (b) (4)	29 Oct 2020 14:44:52

US3412151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:18
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Oct 2020 14:44:52

US3412151

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:18
User entered empty.	Mason Urban (b) (4)	29 Oct 2020 14:44:52

US3412151

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:33:18
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Oct 2020 14:45:06

US3412151

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:03:00
User entered '1'	System	29 Oct 2020 14:45:06

US3412151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 17:07:51

US3412151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '3 Dec 2020'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 17:07:51

US3412151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:26:34
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 17:07:51

US3412151

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 17:07:51

US3412151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 17:08:01

US3412151

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User entered '1'	System	06 Dec 2020 17:08:01

US3412151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	31 Dec 2020 18:03:03

US3412151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '31 Dec 2020'	(b) (4) Mason Urban (b) (4)	31 Dec 2020 18:03:03

US3412151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	31 Dec 2020 18:03:03

US3412151

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	(b) (4) Mason Urban (b) (4)	31 Dec 2020 18:03:03
	(b) (4)	

US3412151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	31 Dec 2020 18:02:45

US3412151

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User entered 'I'	System	31 Dec 2020 18:02:45

US3412151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Jan 2021 16:11:18

US3412151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '29 Jan 2021'	(b) (4) Mason Urban (b) (4)	29 Jan 2021 16:11:18

US3412151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Jan 2021 16:11:18

US3412151

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	(b) (4) Mason Urban (b) (4)	29 Jan 2021 16:11:18
	(b) (4)	

US3412151

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Jan 2021 16:11:22

US3412151

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:11:50
User entered '1'	System	29 Jan 2021 16:11:22

US3412151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 15:26:50

US3412151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '04 Mar 2021'	(b) (4) Andrea Newlands (b) (4)	04 Mar 2021 15:26:50

US3412151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 15:26:50

US3412151

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'VISIT4'	System	04 Mar 2021 15:26:50

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	(b) (4) Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	(b) (4) Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered empty.	System	30 Mar 2021 14:58:17

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45

US3412151

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45

US3412151

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'No (N)'	Andrea Newlands (b) (4)	04 Mar 2021 15:26:58

US3412151

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 15:26:58

US3412151

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 15:27:08

US3412151

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 15:27:08

US3412151

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '07:36'	Andrea Newlands (b) (4)	04 Mar 2021 15:27:08

US3412151

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered '04 Mar 2021 07:36'	System	04 Mar 2021 15:27:08

US3412151

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 15:27:35

US3412151

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:18:45
User entered 'I'	System	04 Mar 2021 15:27:35

US3412151

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:04:37

US3412151

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:04:37

US3412151

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:04:37

US3412151

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'LEFT VM ON 01 APR 2021. Called Back 01 APR 2021.' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:03:36
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	01 Apr 2021 17:05:49
User entered 'Left VM on 01 APR 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:05:49
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	01 Apr 2021 17:04:37
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 17:04:37

US3412151

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 19:18:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:03:40

US3412151

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:18:04
User entered '1'	System	01 Apr 2021 19:03:40

US3412151

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 13:26:51

US3412151

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '4 Jan 2021'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:26:51

US3412151

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	05 Jan 2021 13:26:51

US3412151

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

Form: Visit Date

Generated On: 09 Jun 2021 17:36:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 13:26:51

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '4 Jan 2021'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:30:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:39:22

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4)	09 Apr 2021 08:55:36
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:31:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 22:30:59
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:17:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:39:22

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '4 Jan 2021'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'mRNA-1273 (mRNA-1273)'	Melissa Fuson (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:26:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:22:55
User entered 'mRNA-1273 (mRNA-1273)'	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:26:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:22:55
User entered 'mRNA-1273 (mRNA-1273)'	Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User entered empty.	System	05 Jan 2021 13:28:28

US3412151

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

Form: Unblinding

Generated On: 09 Jun 2021 17:36:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User entered empty.	System	05 Jan 2021 13:28:28

US3412151

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:48

US3412151

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '4 Jan 2021'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:48

US3412151

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '09:51'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:28:48

US3412151

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User entered '4 Jan 2021 09:51'	System	05 Jan 2021 13:28:48

US3412151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:29:04

US3412151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '4 Jan 2021'	(b) (4) Melissa Fuson (b) (4)	05 Jan 2021 13:29:04

US3412151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '09:59'	(b) (4) Melissa Fuson (b) (4) (b) (4)	05 Jan 2021 13:29:04

US3412151

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:10:37
User entered '4 Jan 2021 09:59'	System	05 Jan 2021 13:29:04

US3412151

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:36:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:33
User closed query 'Per CDM: AE #2 is recorded as Fatal, however End of Study/Study Discontinuation form is incomplete. Please update. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:53:14
Query 'Per CDM: AE #2 is recorded as Fatal, however End of Study/Study Discontinuation form is incomplete. Please update. Thank you.' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 15:35:24
User opened query 'Per CDM: AE #2 is recorded as Fatal, however End of Study/Study Discontinuation form is incomplete. Please update. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:56:37
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 201 (22FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 11:14:50
Query 'Per DM CLR: Per Safety Follow Up Diary Day 201 (22FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:04:25

US3412151

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:36:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 201 (22FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	20 Mar 2021 12:01:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Richard Powell (b) (4) (b) (4)	15 Mar 2021 15:32:36
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	24 Feb 2021 15:40:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 20:31:06
	Jacob sekinger (b) (4) (b) (4)	22 Sep 2020 20:29:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Reviewed for Safety.		23 Apr 2021 14:57:28
User entered 'USA-US061-2021-mRNA-1273-P301000017'	System	02 Apr 2021 15:50:15
User entered 'New'	(b) (4), (b) (6)	02 Apr 2021 15:50:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User closed query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:55:24
Query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition i found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:06:43
User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 17:52:49
User coded data point as SOC: Vascular disorders, HLG: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:14:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 20:14:54
Data point term sent to Coder	System	01 Mar 2021 20:14:19
User entered 'Worsening of Aortic Stenosis'	Steven Anderson (b) (4) (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'Yes (Y)'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:49:35
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:48:45
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 05:35:02
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4) (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '5 Feb 2021'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:23:35
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 21:22:12
Signature has been broken.	System	12 Apr 2021 21:22:12
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:22:12
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 21:20:16
User signature succeeded.	System	12 Apr 2021 21:20:16
User entered 'Yes (Y)'	Richard Powell (b) (4)	22 Mar 2021 17:00:40
	(b) (4)	
	Steven Anderson (b) (4)	01 Mar 2021 20:13:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	13 Apr 2021 14:49:39
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:23:35
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Apr 2021 21:20:16
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	12 Apr 2021 21:20:16
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:20:16
User entered '12 Apr 2021' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:20:16
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Apr 2021 21:18:50
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'at this time condition is still ongoing' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:49:09
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	09 Apr 2021 05:35:50
User signature succeeded.	Richard Powell (b) (4) (b) (4)	22 Mar 2021 17:00:40
User entered empty.	Steven Anderson (b) (4) (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:23:35
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 21:20:16
Signature has been broken.	System	12 Apr 2021 21:20:16
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:20:16
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	(b) (4)	12 Apr 2021 21:18:50
User signature succeeded.	System	12 Apr 2021 21:18:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Richard Powell (b) (4)	22 Mar 2021 17:00:40
	(b) (4)	
	Steven Anderson (b) (4)	01 Mar 2021 20:13:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Signature has been broken.	(b) (4)	01 Apr 2021 19:36:28
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'No (N)'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 18:23:18
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'patient currently still in hospital' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 19:36:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). Signature has been broken.	System	01 Apr 2021 19:36:28
User entered '1' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Signature has been broken.	(b) (4)	01 Apr 2021 19:36:28
User entered '31 Mar 2021' reason for change: New Information	(b) (4)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Signature has been broken.	(b) (4)	01 Apr 2021 19:36:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Signature has been broken.	(b) (4)	01 Apr 2021 19:36:28
User entered '1' reason for change: New Information	(b) (4)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 19:36:28
User entered '0' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User closed query 'Per DM CLR: SAE Narrative = HE WAS NOT ABLE TO HAVE SURGERY DUE TO NEW FINDINGS ON ECHOCARDIOGRAM (5 FEB 2021) THAT AORTIC STENOSIS HAS WORSENERD FROM MODERATE TO SEVERE CLASSIFICATION. However, ECHOCARDIOGRAM is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:56:09
Query 'Per DM CLR: SAE Narrative = HE WAS NOT ABLE TO HAVE SURGERY DUE TO NEW FINDINGS ON ECHOCARDIOGRAM (5 FEB 2021) THAT AORTIC STENOSIS HAS WORSENERD FROM MODERATE TO SEVERE CLASSIFICATION. However, ECHOCARDIOGRAM is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:15:58
User opened query 'Per DM CLR: SAE Narrative = HE WAS NOT ABLE TO HAVE SURGERY DUE TO NEW FINDINGS ON ECHOCARDIOGRAM (5 FEB 2021) THAT AORTIC STENOSIS HAS WORSENERD FROM MODERATE TO SEVERE CLASSIFICATION. However, ECHOCARDIOGRAM is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 17:53:12
User entered '1'	Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Signature has been broken.	(b) (4)	01 Apr 2021 19:36:28
User entered '1' reason for change: New Information	(b) (4)	01 Apr 2021 19:36:28
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered '0'	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54
	(b) (4)	

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4)	13 Apr 2021 14:49:45
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'this will not resolve since patient has passed away. please advise what to correct this to' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:24:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:23:35
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:18:50
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:18:50
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 05:36:38
User signature succeeded.	Richard Powell (b) (4) (b) (4)	22 Mar 2021 17:00:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	01 Mar 2021 20:13:54

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User signature succeeded.	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered empty.	(b) (4) Steven Anderson (b) (4)	01 Mar 2021 20:13:54

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:49:54
User entered 'SPOKE TO SUBJECT ON 23-FEB-2021 AT 1440. SUBJECT WAS TO HAVE LEFT SHOULDER JOINT REPLACEMENT. HE WAS NOT ABLE TO HAVE SURGERY DUE TO NEW FINDINGS ON ECHOCARDIOGRAM (5 FEB 2021) THAT AORTIC STENOSIS HAS WORSENERD FROM MODERATE TO SEVERE CLASSIFICATION. SUBJECT WILL SEE CARDIOLOGIST ON MARCH 4TH. AS OF RIGHT NOW SHOULDER SURGERY POST-PONED AND POSSIBLE AORTIC VALVE REPLACEMENT.	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 21:18:50
PATIENT HAD AORTIC VALVE REPLACEMENT SURGERY ON 31 MAR 2021. PT NOT FULLY RECOVERED AS OF 01 APR 2021. SPOKE TO PATIENT'S SPOUSE. update: site was informed today that subject has passed away. Site does not know full details, however, it seems that it was due to the stroke. sit has requested medical records and will update accordingly' reason for change: New Information		
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting medical records' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:49:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 05:37:14
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 19:36:28

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SPOKE TO SUBJECT ON 23-FEB-2021 AT 1440. SUBJECT WAS TO HAVE LEFT SHOULDER JOINT REPLACEMENT. HE WAS NOT ABLE TO HAVE SURGERY DUE TO NEW FINDINGS ON ECHOCARDIOGRAM (5 FEB 2021) THAT AORTIC STENOSIS HAS WORSENERD FROM MODERATE TO SEVERE CLASSIFICATION. SUBJECT WILL SEE CARDIOLOGIST ON MARCH 4TH. AS OF RIGHT NOW SHOULDER SURGERY POST-PONED AND POSSIBLE AORTIC VALVE REPLACEMENT. Patient had Aortic valve replacement surgery on 31 MAR 2021. Pt not fully recovered as of 01 APR 2021. Spoke to patient's spouse.' reason for change: New Information User signature succeeded.	(b) (4), (b) (6)	01 Apr 2021 19:36:28
	Richard Powell (b) (4)	22 Mar 2021 17:00:40
User entered 'spoke to subject on 23-feb-2021 at 1440. subject was to have left shoulder joint replacement. He was not able to have surgery due to new findings on echocardiogram (5 Feb 2021) that aortic stenosis has worsened from moderate to severe classification. subject will see cardiologist on March 4th. As of right now shoulder surgery post-poned and possible aortic valve replacement.'	Steven Anderson (b) (4)	01 Mar 2021 20:13:54

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:36:28
User entered '0'	System	01 Mar 2021 20:13:54

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 20:13:54

US3412151

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 19:36:28

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
Reviewed for Safety.		22 Apr 2021 19:06:02
User entered 'USA-US061-2021-mRNA-1273-P301000017'		02 Apr 2021 15:53:18

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 19:08:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 19:08:40
Data point term sent to Coder	System	01 Apr 2021 19:07:42
User entered 'Stroke'	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Yes (Y)'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'No (N)'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:51:31
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'awaiting records' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 14:50:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 05:31:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '31 Mar 2021'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered empty.		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:24:59
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'End date is after date of death. Please update as appropriate.' (Site from System).		22 Apr 2021 15:35:58
User entered '02 Apr 2021' reason for change: Data Entry Error		22 Apr 2021 15:35:58
User opened query 'End date is after date of death. Please update as appropriate.' (Site from System).	System	22 Apr 2021 15:34:29
User entered '12 Apr 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:24:59
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered empty.		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Grade 4 (Grade 4)'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Yes (Y)'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Death](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The cause of death was reported as stroke. However in the death discharge summary, it is listed as " brain herniation secondary to L MCA CVA". Please confirm the cause of death and update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:55:15
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	13 Apr 2021 14:11:57
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '0'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 18:23:28
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient is still hospitalized' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 19:07:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Apr 2021 19:06:47
User entered '1'	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '31 Mar 2021'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered empty.		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 18:23:30
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'Patient currently still in ICU' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 19:07:34
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	01 Apr 2021 19:06:47
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '1'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '0'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '1'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Not Related (NOT RELATED)'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Not Related (NOT RELATED)'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 03 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable for the event, stroke.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:51:36
Query 'PV Query: As the last dose of mRNA-1273 was given on 03 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable for the event, stroke.' answered with 'this has been updated to not applicable' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:01:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 14:50:34
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 03 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable for the event, stroke.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 05:29:27
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '0'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:55:48
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). User entered '1'	(b) (4), (b) (6)	27 Apr 2021 01:17:52 09 Apr 2021 05:32:15 01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered '0'		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:24:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User entered empty.		01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 01:17:52
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:56:36
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:32:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records faxed today' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:14:41
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'no autopsy was preformed ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 15:36:13
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 14:49:39
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 14:49:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The event was reported as resulting in disability. Please specify and provide details of disability.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:51:41
Query 'PV Query: The event was reported as resulting in disability. Please specify and provide details of disability.' answered with 'subject has passed away due to this sae' (Site from Safety).	Steven Anderson (b) (4)	12 Apr 2021 21:26:51
User entered 'PATIENT WAS IN FOR HEART VALVE REPLACEMENT ON 31 MAR 2021. FOLLOWING SURGERY SOMETIME, PATIENT HAD A STROKE WHILE STILL IN HOSPITAL. PATIENT IS CURRENTLY IN ICU AS OF 01 APR 2021. SPOKE TO PATIENT'S SPOUSE DURING ROUTINE SAFETY CALL DAY 239. this SAE has resulted in subjects death. site knows minimal information however, it seems the stroke is the cause. site requested for medical records and will update information as we learn more' reason for change: Data Entry Error	Steven Anderson (b) (4)	12 Apr 2021 21:26:03
User opened query 'PV Query: The event was reported as resulting in disability. Please specify and provide details of disability.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 05:33:36
User entered 'PATIENT WAS IN FOR HEART VALVE REPLACEMENT ON 31 MAR 2021. FOLLOWING SURGERY SOMETIME, PATIENT HAD A STROKE WHILE STILL IN HOSPITAL. PATIENT IS CURRENTLY IN ICU AS OF 01 APR 2021. Spoke to patient's spouse during routine Safety Call Day 239.' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:15:37
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Apr 2021 19:08:44
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Apr 2021 19:08:44
User entered 'Patient was in for heart valve replacement on 31 MAR 2021. Following surgery sometime, patient had a stroke while still in hospital. Patient is currently in ICU as of 01 APR 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:08:44

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Apr 2021 19:06:47
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:06:47

US3412151

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:06:47

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:33
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User closed query 'Per CDM re-query: Site response noted; However there is no Con Med recorded for 06 SEP 2020 as per previous query (Diary Dose 2, Log line#5). Please confirm if the medication was taken and add the details in CM page else provide explanation in query response. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 05:18:26
Query 'Per CDM re-query: Site response noted; However there is no Con Med recorded for 06 SEP 2020 as per previous query (Diary Dose 2, Log line#5). Please confirm if the medication was taken and add the details in CM page else provide explanation in query response. Thank you' answered with 'no medication was taken ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	21 Oct 2020 18:42:18
User closed query 'Per CDM: Diary Dose 2 Temperature Day, Log Line #5 diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:32:14
User opened query 'Per CDM re-query: Site response noted; However there is no Con Med recorded for 06 SEP 2020 as per previous query (Diary Dose 2, Log line#5). Please confirm if the medication was taken and add the details in CM page else provide explanation in query response. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:32:12

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Diary Dose 2 Temperature Day, Log Line #5 diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	14 Oct 2020 16:59:36
User opened query 'Per CDM: Diary Dose 2 Temperature Day, Log Line #5 diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:23:51
User entered 'Yes (Y)' reason for change: Data Entry Error		21 Aug 2020 16:44:15
User entered 'No (N)'		07 Aug 2020 16:23:03

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 16:45:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:45:14
Data point term sent to Coder	System	21 Aug 2020 16:44:50
User entered 'ASPIRIN'	(b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '81'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:44:42

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 16:46:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:46:16
Data point term sent to Coder	System	21 Aug 2020 16:45:54
User entered 'LOSARTAN'	(b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '10'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:45:10

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 16:48:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 16:48:23
Data point term sent to Coder	System	21 Aug 2020 16:46:56
User entered 'ROSUVASTATIN'	(b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'HYPERLIPIDEMIA'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '5'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:46:20

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: IRBESARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Aug 2020 09:52:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 09:52:49
Data point term sent to Coder	System	21 Aug 2020 16:46:57
User entered 'IRBASARTAN'	(b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '150'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 16:46:50

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 17:12:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:12:35
Data point term sent to Coder	System	14 Oct 2020 17:12:05
User entered 'TYLENOL'	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'SOLICITED INJECTION SITE PAIN'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '500'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'as needed (PRN)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	14 Oct 2020 17:15:37
User entered '07 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:15:37
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Oct 2020 17:11:34
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Oct 2020 17:15:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 17:15:37
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:15:37
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 17:11:34
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4)	14 Oct 2020 17:15:37
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:18:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 17:15:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:15:37
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 17:11:34
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User entered empty.	System	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User entered empty.	System	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:20:51
User entered empty.	System	14 Oct 2020 17:11:34

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:36:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:33
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:13:26
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	21 Oct 2020 18:37:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jacob sekinger (b) (4)	21 Oct 2020 18:36:24
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 16:22:45

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:36

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered 'echocardiogram'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:36

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:36

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:36:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:34:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:36

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:40

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered 'Aortic Valve Replacement'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:40

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:40

US3412151

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:36:59

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:36:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:40

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered 'Death (DEATH)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered 'Adverse event (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:59

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:34:29

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'USA-US061-2021-MRNA-1273-P301000017'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
Un-reviewed for Safety.	System	13 Apr 2021 14:11:57
User entered 'Yes (Y)'	System	13 Apr 2021 14:11:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:53:18
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Richard'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Powell'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'OH'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
User entered 'US'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 19:06:51
User entered '2'	System	13 Apr 2021 14:54:38
User entered '1'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'USA-US061-2021-MRNA-1273-P301000017'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
Un-reviewed for Safety.	System	13 Apr 2021 14:11:57
User entered 'Yes (Y)'	System	13 Apr 2021 14:11:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:53:18
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Richard'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Powell'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'OH'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
User entered 'US'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 19:06:51
User entered '2'	System	13 Apr 2021 14:54:38
User entered '1'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:59

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '02/Apr/2021 11:54'	(b) (4) System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:36:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:54:52
User entered '1'		02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'USA-US061-2021-MRNA-1273-P301000017'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
Un-reviewed for Safety.	System	13 Apr 2021 14:11:57
User entered 'Yes (Y)'	System	13 Apr 2021 14:11:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:53:18
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Richard'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Powell'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'OH'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
User entered 'US'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 19:06:51
User entered '2'	System	13 Apr 2021 14:54:38
User entered '1'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:59

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
User entered '13/Apr/2021 10:54'	(b) (4) System	13 Apr 2021 14:54:38

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:36:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 14:54:52
User entered '1'		3 Apr 2021 14:54:38

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'USA-US061-2021-MRNA-1273-P301000017'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
Un-reviewed for Safety.	System	13 Apr 2021 14:11:57
User entered 'Yes (Y)'	System	13 Apr 2021 14:11:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:53:18
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'No (N)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Yes (Y)'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Richard'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'Powell'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:53:52
User entered 'OH'	System	02 Apr 2021 15:50:15

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:26:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:54:52
User entered 'US'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 19:06:51
User entered '2'	System	13 Apr 2021 14:54:38
User entered '1'	System	02 Apr 2021 15:54:14

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:59

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered '22/Apr/2021 15:06'	(b) (4) System	22 Apr 2021 19:06:51

US3412151

Folder: SAE USA-US061-2021-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:36:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:06:51