

US3412118 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:31:52

All time stamps listed in this document are displayed in GMT

US3412118

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Participant ID

US3412118

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

US3412118

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3412118

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
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

US3412118

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Date of Informed Consent (*dd MMM yyyy*) 4 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3412118

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412118

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Were any significant conditions reported?

Yes ☒
No ☐

US3412118

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

Condition	PAIN IN HIP AND LEG
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3412118

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

Condition	LEG CRAMPS (RIGHT)
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3412118

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

Condition	AMPUTATION BELOW RIGHT KNEE
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3412118

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Apr 2021 13:30:13

Generated On: 09 Jun 2021 17:31:52

Condition	PERIPHERAL VASCULAR DISEASE
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3412118

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 09:25
Height (<i>xxx.x</i>)	171.0 cm
Weight (<i>xxx.x</i>)	95.9 kg
BMI (<i>xxx.x</i>)	32.79642 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)	

US3412118

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 AUG 2020

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

US3412118

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

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

DOES NOT WORK SEE'S
BROTHER AND SISTER ON A
REGULAR BASES

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

16 of 2425

US3412118

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

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)	False
Other	True
Specify	HIGH RISK COUNTY

US3412118

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	VISIT1

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 100872

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 ☒

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Height	ND - Not Done
Weight	ND - Not Done

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 09:25
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

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 (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 11:00
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

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.

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 10:20 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 10:20

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

US3412118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 AUG 2020

Collection time (00:00-23:59)

09:34 (24 HR)

Collection date and time (derived)

4 AUG 2020 09:34

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Collection date (dd MMM yyyy)			4 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:30	4 AUG 2020 09:30
Nasopharyngeal Swab 2	No		

US3412118

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 11:08

PC Open Date & Time

04 AUG 2020 10:40

PC Close Date & Time

04 AUG 2020 13:10

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	04 AUG 2020 19:35
PC Open Date & Time	04 AUG 2020 14:05
PC Close Date & Time	05 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 19:42

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 19:59

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 19:33

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 19:18

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

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

97.6 °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

09 AUG 2020 19:27

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:29

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 11:12

PC Open Date & Time

04 AUG 2020 10:40

PC Close Date & Time

04 AUG 2020 13:10

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 19:36

PC Open Date & Time

04 AUG 2020 14:05

PC Close Date & Time

05 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 19:43

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 20:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:33

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 19:19

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:27

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:30

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 ☐

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 11:13
PC Open Date & Time	04 AUG 2020 10:40
PC Close Date & Time	04 AUG 2020 13:10

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 ☐

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 19:38
PC Open Date & Time	04 AUG 2020 14:05
PC Close Date & Time	05 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 ☒

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 19:44
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:01
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:34
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:20
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:28
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:31
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:31
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 09:55 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 09:55

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

US3412118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	09:24 (24 HR)
Collection date and time (derived)	01 SEP 2020 09:24

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:27	01 SEP 2020 09:27
Nasopharyngeal Swab 2	No		

US3412118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 10:33

PC Open Date & Time

01 SEP 2020 10:15

PC Close Date & Time

01 SEP 2020 12:45

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	01 SEP 2020 19:03
PC Open Date & Time	01 SEP 2020 13:40
PC Close Date & Time	02 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:13

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 19:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 19:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:10

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

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

97.6 °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

07 SEP 2020 19:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 10:33

PC Open Date & Time

01 SEP 2020 10:15

PC Close Date & Time

01 SEP 2020 12:45

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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

01 SEP 2020 19:03

PC Open Date & Time

01 SEP 2020 13:40

PC Close Date & Time

02 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:13

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 19:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:10

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 19:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 19:13

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 ☐

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:34
PC Open Date & Time	01 SEP 2020 10:15
PC Close Date & Time	01 SEP 2020 12:45

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 ☐

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 19:04
PC Open Date & Time	01 SEP 2020 13:40
PC Close Date & Time	02 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 ☒

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:14
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 ☒

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 ☒

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2425

EAB) (1725)

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 ☒

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:13
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:48:40

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:36:33

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:36:33

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:36:49

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

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) _____

US3412118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

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.

US3412118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	08:24 (24 HR)
Collection date and time (derived)	29 SEP 2020 08:24

US3412118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:36:50

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 13:21:49
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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 13 OCT 2020 12:14:31

Patient Cloud Open Date & Time 11 OCT 2020 00:01

Patient Cloud Close Date & Time 15 OCT 2020 23:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

19 OCT 2020 11:49:53

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 19:28:58

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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	11 NOV 2020 16:32:30
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

17 NOV 2020 14:08:08

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

23 NOV 2020 12:43:43

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 18:04:20

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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 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 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 DEC 2020 14:11:01
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

11 DEC 2020 19:01:25

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 12:09:38

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 18:06:41

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

02 JAN 2021 12:19:29

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 14:13:56
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 16:27:52

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 07:48:01

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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 08:52:26
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 08:21:41

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

26 FEB 2021 10:42:21

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

07 MAR 2021 15:52:49

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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	12 MAR 2021 19:53:05
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 10:43:26

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 20:01:54

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 19:56:00

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 20:14:58

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:13:56

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 00:08:57

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3412118

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:31:52

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		03 MAR 2021 09:55:01

US3412118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:31:38

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:31:38

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

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

Visit date (dd MMM yyyy)	03 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 09:08
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412118

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

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.

US3412118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	03 MAR 2021 09:30

US3412118

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

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

Comments FULL MAILBOX 30 MAR 2021.
CONTACT MADE 31 MAR 2021.

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Date of Contact	1 DEC 2020
Time of Contact	11:00
Date and Time of Contact (derived)	1 DEC 2020 11:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

320 of 2425

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	36.6 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

324 of 2425

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 2425

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	3 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

332 of 2425

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 2425

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Date of Visit	1 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	1 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	3 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3412118

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 DEC 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	1 DEC 2020 11:00
Height (xxx.x)	171 cm
Weight (xxx.x)	99.5 kg
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412118

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 DEC 2020

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

US3412118

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

1 DEC 2020

US3412118

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3412118

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

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

US3412118

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Height	171.5 cm
Weight	102.7 kg
BMI (xxx.x)	34.91742

US3412118

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Height	171.5 cm
Weight	102.7 kg
BMI (xxx.x)	34.91742
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 11:05
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Height	171.5 cm
Weight	102.7 kg
BMI (xxx.x)	34.91742
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 11:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

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

US3412118

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 6 JAN 2021

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 11:22

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

US3412118

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	6 JAN 2021
-------------------------------	------------

Collection time (00:00-23:59)	11:17 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	6 JAN 2021 11:17
------------------------------------	------------------

US3412118

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	11:13
Collection Date and Time (derived)	6 JAN 2021 11:13

US3412118

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:31:38

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:31:38

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:17

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:21:17

Generated On: 09 Jun 2021 17:31:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 09:13
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:21:17

Generated On: 09 Jun 2021 17:31:52

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 10:38
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412118

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:17

Generated On: 09 Jun 2021 17:31:52

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.

US3412118

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:21:17

Generated On: 09 Jun 2021 17:31:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 03 FEB 2021

What was the treatment time? (00:00-23:59) 09:57 (24 HR)

Treatment Date and Time (derived) 03 FEB 2021 09:57

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

What was the frequency of the study treatment dosing? ONCE

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

US3412118

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:11

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:31:38

Generated On: 09 Jun 2021 17:31:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412118

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:31:38

Generated On: 09 Jun 2021 17:31:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412118

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:08 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 09:08
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412118

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

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.

US3412118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	03 MAR 2021 09:30

US3412118

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:30:34

Generated On: 09 Jun 2021 17:31:52

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

AEID	USA-US061-2020-MRNA-1273-P30 1000015
Adverse event	RIGHT FEMORAL ARTERY OCCLUSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 NOV 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	371 of 2425

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

SUBJECT PRESENTED TO HIS
PHYSICIAN POST ONSET OF
RIGHT LEG CRAMPING AND
PAIN ON 30OCT2020. RIGHT
FEMORAL ARTERY OCCLUSION
WAS DIAGNOSED AND
SUBJECT UNDERWENT RIGHT
FEMORAL ENDARTERECTOMY
ON 19NOV2020. SUBJECT
NOTIFIED OUR SITE OF THIS ON
01DEC2020 @10:45AM.
SURGERY WAS PERFORMED AT
KETTERY MEDICAL CENTER.
PROCEDURES PERFORMED:
RIGHT COMMON FEMORAL
ENDARTERECTOMY WITH
PATCH ANGIOPLASTY, RIGHT
PROFUNDOPLASTY, RIGHT
PROFUNDA THROMBECTOMY,
PRAVEENA WOUND VAC RIGHT
GROIN. MEDICAL RECORDS
WERE RECEIVED AND
REVIEWED. ANESTHESIA
NOTES WERE REQUESTED.
SUBJECT'S HOSPITALIZATION
REQUIRE 1 OVER NIGHT
ADMISSION. HE WAS
RELEASED AND COMPLETELY
RECOVERED FROM THE
PROCEDURE AND RETURNED
TO BASELINE. ANESTHESIA
AND PERIOPERATIVE
ANTIBIOTIC DETAILS NOT
AVAILABLE.

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

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

AEID	
Adverse event	URI
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2425

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2425

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 14:09:24

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 14:40:13

Generated On: 09 Jun 2021 17:31:52

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

Yes ☒

No ☐

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication CALCIUM DISODIUM
VERSENATE

Prophylaxis Yes ☐
No ☒

Indication BONE HEALTH

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication HIP AND LEG PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication LOSARTAN/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 100/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication LEG CRAMPS

Dose per administration 250

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

385 of 2425

EAB) (1725)

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

387 of 2425

EAB) (1725)

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication HIP AND LEG PAIN

Dose per administration 100/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

397 of 2425

EAB) (1725)

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication HYDROCODONE

Prophylaxis Yes ☐
No ☒

Indication HIP AND LEG PAIN

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

Name of Medication TEMUZEPAIN

Prophylaxis Yes ☐
No ☒

Indication HIP AND LEG PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 14:16:30

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:34:34

Generated On: 09 Jun 2021 17:31:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:34:33

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 NOV 2020	RIGHT COMMON FEMORAL ENDARTERECTOMY WITH PATCH ANGIOPLASTY	Adverse Event	
19 NOV 2020	RIGHT PROFUNDOPLASTY TO THE FOURTH ORDER PROFUNDA	Adverse Event	
19 NOV 2020	RIGHT PROFUNDA THROMBECTOMY	Adverse Event	
19 NOV 2020	APPLICATION OF PRAVEENA WOUND VAC RIGHT GROIN 13 CM	Adverse Event	
19 NOV 2020	PATHOLOGY REPORT FOR RIGHT FEMORAL LYMPH NODE.	Diagnostic	
19 NOV 2020	PATHOLOGY REPORT FOR RIGHT FEMORAL PLAQUE WITH ATHEROMATOUS PLAQUE WITH CALCIFICATION	Diagnostic	

US3412118

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:31:52

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

US3412118

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:31:52

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

SAEID	USA-US061-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

SAEID	USA-US061-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/DEC/2020 19:06
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.	True

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

SAEID	USA-US061-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/FEB/2021 08:55
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

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

SAEID	USA-US061-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAR/2021 11:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:21:18

Generated On: 09 Jun 2021 17:31:52

SAEID	USA-US061-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/APR/2021 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412118 (Prod: New Horizons Clinical Research)

US3412118

Form: Participant Creation

Generated On: 09 Jun 2021 17:31:52

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'US3412118'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:09:40

US3412118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:58:56

US3412118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:09:41

US3412118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:58:56

US3412118

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'SCRN'	System	04 Aug 2020 13:58:56

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:09:42

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '56'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'YEARS'	System	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '56'	System	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	21 Sep 2020 16:33:28
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 13:59:55

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Aug 2020'	System	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2020'	System	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:00:54

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:09:41

US3412118

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'I'	System	04 Aug 2020 14:01:31

US3412118

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:01:31

US3412118

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:31:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:36:22

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
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)	14 Aug 2020 16:39:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:39:23
Data point term sent to Coder	System	14 Aug 2020 16:38:16
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:37:59
User entered 'HYPERLIPIDEMIA'		14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Jan 2018'	System	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2018'	System	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:37:31

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:40:25
Data point term sent to Coder	System	14 Aug 2020 16:39:21
User entered 'GERD'	(b) (4), (b) (6)	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Jan 2018'	System	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2018'	System	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:38:24

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 16:40:25
Data point term sent to Coder	System	14 Aug 2020 16:39:21
User entered 'BPH'	(b) (4), (b) (6)	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Jan 2017'	System	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2017'	System	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:38:40

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 13:16:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 13:16:39
Data point term sent to Coder	System	14 Aug 2020 16:40:25
User entered 'PAIN IN HIP AND LEG'	(b) (4), (b) (6)	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	14 Aug 2020 16:39:31

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User closed query 'Please consider entering Right below knee amputation in 2002, ' (Site from CRA).	(b) (4)	19 Mar 2021 15:28:37
Query 'Please consider entering Right below knee amputation in 2002, ' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	16 Mar 2021 13:57:40
User opened query 'Please consider entering Right below knee amputation in 2002, ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 17:40:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 14:20:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 14:20:47
User closed query 'Per DM CLR: Please update the condition to include the laterality of LEG CRAMPS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:57:10
Data point term sent to Coder	System	26 Oct 2020 18:32:49
Query 'Per DM CLR: Please update the condition to include the laterality of LEG CRAMPS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Mason Urban (b) (4)	26 Oct 2020 18:32:35
Coding entries removed.	Mason Urban (b) (4)	26 Oct 2020 18:32:28
User entered 'LEG CRAMPS (RIGHT)' reason for change: Data Entry Error	Mason Urban (b) (4)	26 Oct 2020 18:32:28

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the laterality of LEG CRAMPS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:42:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 15:54:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	19 Oct 2020 15:54:40
Data point term sent to Coder	System	19 Oct 2020 15:53:28
User entered 'LEG CRAMPS'	Mason Urban (b) (4)	19 Oct 2020 15:53:11
	(b) (4)	

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'UN Apr 2020'	Mason Urban (b) (4)	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Mason Urban (b) (4)	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	Mason Urban (b) (4)	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Mason Urban (b) (4)	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Apr 2020'	System	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2020'	System	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	19 Oct 2020 15:53:11

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User closed query 'Per CDM RQ: Response noted. However please clarify response as there is no associated condition leading to this procedure recorded in the Medical History. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:40
Query 'Per CDM RQ: Response noted. However please clarify response as there is no associated condition leading to this procedure recorded in the Medical History. Thank you.' answered with 'there is no associated medical condition. this was due to a motor vehicle accident ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 13:03:54
User opened query 'Per CDM RQ: Response noted. However please clarify response as there is no associated condition leading to this procedure recorded in the Medical History. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:49:22
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).		05 Apr 2021 13:48:16
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'information has been updated' (Site from DM).		31 Mar 2021 20:28:37
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).		29 Mar 2021 04:43:20
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Leg amputation, LLT: Below knee amputation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:48:47

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Mar 2021 08:48:47
User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 13:58:04
User entered 'amputation below right knee'	Andrea Newlands (b) (4)	16 Mar 2021 13:57:30
	(b) (4)	

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User closed query '2002? Please confirm' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:49:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
Query '2002? Please confirm' answered with 'information has been updated' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
User opened query '2002? Please confirm' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 20:28:18
User entered 'un UNK 2008'	(b) (4)	19 Mar 2021 15:27:55
	Andrea Newlands (b) (4)	16 Mar 2021 13:57:30
	(b) (4)	

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User closed query '2002? Please confirm' (Site from CRA).	(b) (4)	20 Apr 2021 16:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
Query '2002? Please confirm' answered with 'information has been updated' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 20:28:24
User opened query '2002? Please confirm' (Site from CRA).	(b) (4)	19 Mar 2021 15:28:06
User entered 'un UNK 2008'	Andrea Newlands (b) (4)	16 Mar 2021 13:57:30
	(b) (4)	

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered '0'	Andrea Newlands (b) (4)	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Jan 2008'	System	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2008'	System	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Jan 2008'	System	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2008'	System	16 Mar 2021 13:57:30

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 20:15:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 20:15:49
Data point term sent to Coder	System	31 Mar 2021 20:13:51
User entered 'PERIPHERAL VASCULAR DISEASE'	(b) (4), (b) (6)	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered 'UN Jun 2020'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:13
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'Jun 2020'	System	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '2020'	System	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:52

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered empty.	System	31 Mar 2021 20:13:49

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '09:25'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '4 Aug 2020 09:25'	System	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '171.0' cm	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12
DataPoint set to visible.	System	04 Aug 2020 14:01:31

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '95.9' kg	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12
DataPoint set to visible.	System	04 Aug 2020 14:01:31

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
Amendment Manager: User entered '32.79642'	System	16 Sep 2020 23:42:06
User entered '32.8'	System	14 Aug 2020 16:51:12
DataPoint set to visible.	System	04 Aug 2020 14:01:31

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'kg/m2'	System	14 Aug 2020 16:51:12
DataPoint set to visible.	System	04 Aug 2020 14:01:31

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 20:42:36
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).		14 Aug 2020 16:51:16
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 16:51:12
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'bpm'	System	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'breaths/min'	System	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'mmHg'	System	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'mmHg'	System	14 Aug 2020 16:51:12

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38

US3412118

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38

US3412118

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:51:30

US3412118

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:57:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 13:49:22
User entered '4 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 16:51:30

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'does not work see's brother and sister on a regular bases'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '0'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'I'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'High risk county'	Jacob sekinger (b) (4)	21 Sep 2020 16:46:00

US3412118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:02:27

US3412118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:02:27

US3412118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:02:27

US3412118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'VISIT1'	System	04 Aug 2020 14:02:27

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:46:05

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:53:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:53:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 13:46:05
User entered '100872' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:46:05

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:46:05

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
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 Aug 2020 16:54:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:54:27
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 14:02:42
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 14:02:42

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
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 Aug 2020 16:54:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:54:27
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 14:02:42
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 14:02:42

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
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 Aug 2020 16:54:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:54:27
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 14:02:42
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 14:02:42

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
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 Aug 2020 16:54:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:54:27
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 14:02:42
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 14:02:42

US3412118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:52

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
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 Aug 2020 16:54:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 16:54:27
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 14:02:42
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 14:02:42

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Pre-Dose (PREDOSE)'		14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:25'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '4 Aug 2020 09:25'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '80'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'bpm'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '16'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'breaths/min'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '130'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '82'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Post-Dose (POSTDOSE)'		14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 11:03:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'NA' (Site from System).		14 Aug 2020 16:57:53
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).		14 Aug 2020 16:57:43
User entered '11:00'	(b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '4 Aug 2020 11:00'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '68'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'bpm'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '14'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'breaths/min'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '128'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '88'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	14 Aug 2020 16:57:43

US3412118

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:06

US3412118

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:06

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '10:20'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '4 Aug 2020 10:20'	System	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'ONCE'	System	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 14:26:03

US3412118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:34

US3412118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:34

US3412118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:34'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:34

US3412118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '4 Aug 2020 09:34'	System	14 Aug 2020 16:58:34

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '4 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:30'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '4 Aug 2020 09:30'	System	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	14 Aug 2020 16:58:57

US3412118

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:59:02

US3412118

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'I'	System	14 Aug 2020 16:59:02

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:07:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c0db4603-1067-4e48-803e-c658f6a79ad7'	System	04 Aug 2020 15:08:47
User entered 'Yes (Y)'	System	04 Aug 2020 15:08:47

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:07:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c0db4603-1067-4e48-803e-c658f6a79ad7' User entered '98.3'	System	04 Aug 2020 15:08:47
	System	04 Aug 2020 15:08:47

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:08:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c0db4603-1067-4e48-803e-c658f6a79ad7'	System	04 Aug 2020 15:08:47
User entered 'No (N)'	System	04 Aug 2020 15:08:47

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:08:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c0db4603-1067-4e48-803e-c658f6a79ad7'	System	04 Aug 2020 15:08:47
User entered '04 Aug 2020 11:08'	System	04 Aug 2020 15:08:47

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 10:40'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 13:10'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:34:51', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11c4196f-7d07-435e-b197-b74750dc1c6a' User entered 'Yes (Y)'	System	04 Aug 2020 23:35:32
	System	04 Aug 2020 23:35:32

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:34:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11c4196f-7d07-435e-b197-b74750dc1c6a' User entered '98.7'	System	04 Aug 2020 23:35:32
	System	04 Aug 2020 23:35:32

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:35:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11c4196f-7d07-435e-b197-b74750dc1c6a' User entered 'No (N)'	System	04 Aug 2020 23:35:32
	System	04 Aug 2020 23:35:32

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:35:30', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11c4196f-7d07-435e-b197-b74750dc1c6a' User entered '04 Aug 2020 19:35'	System	04 Aug 2020 23:35:32
	System	04 Aug 2020 23:35:32

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 14:05'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 2'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:42:04', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '29dcb3a5-b38b-4fa0-8c3d-bd553bd55c6f' User entered 'Yes (Y)'	System	05 Aug 2020 23:42:40
	System	05 Aug 2020 23:42:40

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:42:13', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '29dcb3a5-b38b-4fa0-8c3d-bd553bd55c6f' User entered '97.6'	System	05 Aug 2020 23:42:40
	System	05 Aug 2020 23:42:40

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:42:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '29dcb3a5-b38b-4fa0-8c3d-bd553bd55c6f' User entered 'No (N)'	System	05 Aug 2020 23:42:40
	System	05 Aug 2020 23:42:40

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:42:38', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '29dcb3a5-b38b-4fa0-8c3d-bd553bd55c6f' User entered '05 Aug 2020 19:42'	System	05 Aug 2020 23:42:40
	System	05 Aug 2020 23:42:40

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 3'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T19:59:11', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cfa217b6-d228-4529-bfed-c3db9d9725d2'	System	06 Aug 2020 23:59:38
User entered 'Yes (Y)'	System	06 Aug 2020 23:59:38

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T19:59:18', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cfa217b6-d228-4529-bfed-c3db9d9725d2' User entered '98.2'	System	06 Aug 2020 23:59:38
	System	06 Aug 2020 23:59:38

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T19:59:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cfa217b6-d228-4529-bfed-c3db9d9725d2'	System	06 Aug 2020 23:59:38
User entered 'No (N)'	System	06 Aug 2020 23:59:38

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T19:59:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cfa217b6-d228-4529-bfed-c3db9d9725d2'	System	06 Aug 2020 23:59:38
User entered '06 Aug 2020 19:59'	System	06 Aug 2020 23:59:38

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 4'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:32:48', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '44830f03-ca41-4283-b0d6-8795aa8b54d7' User entered 'Yes (Y)'	System	07 Aug 2020 23:33:14
	System	07 Aug 2020 23:33:14

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:32:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '44830f03-ca41-4283-b0d6-8795aa8b54d7' User entered '98.4'	System	07 Aug 2020 23:33:14
	System	07 Aug 2020 23:33:14

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '44830f03-ca41-4283-b0d6-8795aa8b54d7' User entered 'No (N)'	System	07 Aug 2020 23:33:14
	System	07 Aug 2020 23:33:14

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:13', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '44830f03-ca41-4283-b0d6-8795aa8b54d7'	System	07 Aug 2020 23:33:14
User entered '07 Aug 2020 19:33'	System	07 Aug 2020 23:33:14

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 5'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:18:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5ca03a08-96ba-4a18-a41a-ecdccad190c5' User entered 'Yes (Y)'	System	08 Aug 2020 23:18:55
	System	08 Aug 2020 23:18:55

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:18:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5ca03a08-96ba-4a18-a41a-ecdccad190c5' User entered '97.8'	System	08 Aug 2020 23:18:55
	System	08 Aug 2020 23:18:55

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:18:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5ca03a08-96ba-4a18-a41a-ecdccad190c5'	System	08 Aug 2020 23:18:55
User entered 'No (N)'	System	08 Aug 2020 23:18:55

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:18:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5ca03a08-96ba-4a18-a41a-ecdccad190c5' User entered '08 Aug 2020 19:18'	System	08 Aug 2020 23:18:55
	System	08 Aug 2020 23:18:55

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 6'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:26:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7c58d6b9-18b4-4c32-9d3d-a57311f8e936' User entered 'Yes (Y)'	System	09 Aug 2020 23:27:03
	System	09 Aug 2020 23:27:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:26:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7c58d6b9-18b4-4c32-9d3d-a57311f8e936'	System	09 Aug 2020 23:27:03
User entered '97.6'	System	09 Aug 2020 23:27:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:26:55', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7c58d6b9-18b4-4c32-9d3d-a57311f8e936'	System	09 Aug 2020 23:27:03
User entered 'No (N)'	System	09 Aug 2020 23:27:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7c58d6b9-18b4-4c32-9d3d-a57311f8e936'	System	09 Aug 2020 23:27:03
User entered '09 Aug 2020 19:27'	System	09 Aug 2020 23:27:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 7'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:29:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c388297f-81aa-4068-bcc6-78540c85fd29'	System	10 Aug 2020 23:29:57
User entered 'Yes (Y)'	System	10 Aug 2020 23:29:57

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:29:40', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c388297f-81aa-4068-bcc6-78540c85fd29' User entered '98.7'	System	10 Aug 2020 23:29:57
	System	10 Aug 2020 23:29:57

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:29:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c388297f-81aa-4068-bcc6-78540c85fd29'	System	10 Aug 2020 23:29:57
User entered 'No (N)'	System	10 Aug 2020 23:29:57

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:29:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c388297f-81aa-4068-bcc6-78540c85fd29'	System	10 Aug 2020 23:29:57
User entered '10 Aug 2020 19:29'	System	10 Aug 2020 23:29:57

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:11:37', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf26be71-d4d5-47ff-a7f1-d5016d81026f' User entered 'None (1)'	System	04 Aug 2020 15:12:42
	System	04 Aug 2020 15:12:42

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:11:46', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf26be71-d4d5-47ff-a7f1-d5016d81026f' User entered 'No (N)'	System	04 Aug 2020 15:12:42
	System	04 Aug 2020 15:12:42

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:11:59', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf26be71-d4d5-47ff-a7f1-d5016d81026f' User entered 'No (N)'	System	04 Aug 2020 15:12:42
	System	04 Aug 2020 15:12:42

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:12:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf26be71-d4d5-47ff-a7f1-d5016d81026f' User entered 'None (1)'	System	04 Aug 2020 15:12:42
	System	04 Aug 2020 15:12:42

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:12:37', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf26be71-d4d5-47ff-a7f1-d5016d81026f' User entered '04 Aug 2020 11:12'	System	04 Aug 2020 15:12:42
	System	04 Aug 2020 15:12:42

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 10:40'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 13:10'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:35:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11040bd5-81dd-43b7-ad52-76ef538d29df' User entered 'None (1)'	System	04 Aug 2020 23:36:53
	System	04 Aug 2020 23:36:53

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:36:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11040bd5-81dd-43b7-ad52-76ef538d29df' User entered 'No (N)'	System	04 Aug 2020 23:36:53
	System	04 Aug 2020 23:36:53

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:36:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11040bd5-81dd-43b7-ad52-76ef538d29df' User entered 'No (N)'	System	04 Aug 2020 23:36:53
	System	04 Aug 2020 23:36:53

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:36:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11040bd5-81dd-43b7-ad52-76ef538d29df' User entered 'None (1)'	System	04 Aug 2020 23:36:53
	System	04 Aug 2020 23:36:53

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:36:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '11040bd5-81dd-43b7-ad52-76ef538d29df' User entered '04 Aug 2020 19:36'	System	04 Aug 2020 23:36:53
	System	04 Aug 2020 23:36:53

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 14:05'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 2'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:42:50', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dffa03cf-a4e6-446e-838f-5244b384d407'	System	05 Aug 2020 23:43:23
User entered 'None (1)'	System	05 Aug 2020 23:43:23

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:42:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dffa03cf-a4e6-446e-838f-5244b384d407'	System	05 Aug 2020 23:43:23
User entered 'No (N)'	System	05 Aug 2020 23:43:23

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dffa03cf-a4e6-446e-838f-5244b384d407' User entered 'No (N)'	System	05 Aug 2020 23:43:23
	System	05 Aug 2020 23:43:23

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:12', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dffa03cf-a4e6-446e-838f-5244b384d407'	System	05 Aug 2020 23:43:23
User entered 'None (1)'	System	05 Aug 2020 23:43:23

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dffa03cf-a4e6-446e-838f-5244b384d407'	System	05 Aug 2020 23:43:23
User entered '05 Aug 2020 19:43'	System	05 Aug 2020 23:43:23

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 3'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T19:59:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67bf7816-d199-42be-becc6-4bf87c159c5f' User entered 'None (1)'	System	07 Aug 2020 00:00:22
	System	07 Aug 2020 00:00:22

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T19:59:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67bf7816-d199-42be-becc6-4bf87c159c5f' User entered 'No (N)'	System	07 Aug 2020 00:00:22
	System	07 Aug 2020 00:00:22

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67bf7816-d199-42be-becc6-4bf87c159c5f' User entered 'No (N)'	System	07 Aug 2020 00:00:22
	System	07 Aug 2020 00:00:22

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:08', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67bf7816-d199-42be-becc6-4bf87c159c5f' User entered 'None (1)'	System	07 Aug 2020 00:00:22
	System	07 Aug 2020 00:00:22

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67bf7816-d199-42be-bec6-4bf87c159c5f' User entered '06 Aug 2020 20:00'	System	07 Aug 2020 00:00:22
	System	07 Aug 2020 00:00:22

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 4'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ddabfee6-779b-499d-9dbe-167bf541f243'	System	07 Aug 2020 23:33:59
User entered 'None (1)'	System	07 Aug 2020 23:33:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:31', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ddabfee6-779b-499d-9dbe-167bf541f243'	System	07 Aug 2020 23:33:59
User entered 'No (N)'	System	07 Aug 2020 23:33:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:34', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ddabfee6-779b-499d-9dbe-167bf541f243' User entered 'No (N)'	System	07 Aug 2020 23:33:59
	System	07 Aug 2020 23:33:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ddabfee6-779b-499d-9dbe-167bf541f243' User entered 'None (1)'	System	07 Aug 2020 23:33:59
	System	07 Aug 2020 23:33:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:33:55', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ddabfee6-779b-499d-9dbe-167bf541f243' User entered '07 Aug 2020 19:33'	System	07 Aug 2020 23:33:59
	System	07 Aug 2020 23:33:59

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 5'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:08', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '10f946dd-e57e-486d-9871-c30dd5fb8683' User entered 'None (1)'	System	08 Aug 2020 23:19:33
	System	08 Aug 2020 23:19:33

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:11', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '10f946dd-e57e-486d-9871-c30dd5fb8683' User entered 'No (N)'	System	08 Aug 2020 23:19:33
	System	08 Aug 2020 23:19:33

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:14', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '10f946dd-e57e-486d-9871-c30dd5fb8683' User entered 'No (N)'	System	08 Aug 2020 23:19:33
	System	08 Aug 2020 23:19:33

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '10f946dd-e57e-486d-9871-c30dd5fb8683' User entered 'None (1)'	System	08 Aug 2020 23:19:33
	System	08 Aug 2020 23:19:33

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '10f946dd-e57e-486d-9871-c30dd5fb8683' User entered '08 Aug 2020 19:19'	System	08 Aug 2020 23:19:33
	System	08 Aug 2020 23:19:33

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 6'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:07', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '39948760-e6fd-4df2-8cf5-159473e81ddb' User entered 'None (1)'	System	09 Aug 2020 23:27:27
	System	09 Aug 2020 23:27:27

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '39948760-e6fd-4df2-8cf5-159473e81ddb' User entered 'No (N)'	System	09 Aug 2020 23:27:27
	System	09 Aug 2020 23:27:27

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:13', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '39948760-e6fd-4df2-8cf5-159473e81ddb' User entered 'No (N)'	System	09 Aug 2020 23:27:27
	System	09 Aug 2020 23:27:27

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '39948760-e6fd-4df2-8cf5-159473e81ddb' User entered 'None (1)'	System	09 Aug 2020 23:27:27
	System	09 Aug 2020 23:27:27

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:24', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '39948760-e6fd-4df2-8cf5-159473e81ddb' User entered '09 Aug 2020 19:27'	System	09 Aug 2020 23:27:27
	System	09 Aug 2020 23:27:27

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 7'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e69b703e-3228-4801-95ee-d0d752a1ede2' User entered 'None (1)'	System	10 Aug 2020 23:30:25
	System	10 Aug 2020 23:30:25

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e69b703e-3228-4801-95ee-d0d752a1ede2' User entered 'No (N)'	System	10 Aug 2020 23:30:25
	System	10 Aug 2020 23:30:25

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e69b703e-3228-4801-95ee-d0d752a1ede2' User entered 'No (N)'	System	10 Aug 2020 23:30:25
	System	10 Aug 2020 23:30:25

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:15', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e69b703e-3228-4801-95ee-d0d752a1ede2' User entered 'None (1)'	System	10 Aug 2020 23:30:25
	System	10 Aug 2020 23:30:25

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e69b703e-3228-4801-95ee-d0d752a1ede2' User entered '10 Aug 2020 19:30'	System	10 Aug 2020 23:30:25
	System	10 Aug 2020 23:30:25

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:12:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4'	System	04 Aug 2020 15:13:47
User entered 'None (0)'	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4'	System	04 Aug 2020 15:13:47
User entered 'None (0)'	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4' User entered 'None (0)'	System	04 Aug 2020 15:13:47
	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:09', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4'	System	04 Aug 2020 15:13:47
User entered 'None (0)'	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:12', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4'	System	04 Aug 2020 15:13:47
User entered 'None (0)'	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:15', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4' User entered 'None (0)'	System	04 Aug 2020 15:13:47
	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4' User entered 'No (N)'	System	04 Aug 2020 15:13:47
	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T11:13:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '72ed77f3-79be-4dca-bc34-cf02a13821e4' User entered '04 Aug 2020 11:13'	System	04 Aug 2020 15:13:47
	System	04 Aug 2020 15:13:47

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 10:40'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 13:10'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:37:04', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'None (0)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:37:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'None (0)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:37:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'None (0)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:37:26', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'None (0)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:37:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'None (0)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:37:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'None (0)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:38:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered 'No (N)'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-04T19:38:28', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5fd8a8a9-8cbf-479f-b5aa-b56f41464586' User entered '04 Aug 2020 19:38'	System	04 Aug 2020 23:38:30
	System	04 Aug 2020 23:38:30

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Aug 2020 14:05'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 2'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:37', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'None (0)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'None (0)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'None (0)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:48', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'None (0)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:51', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'None (0)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:43:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'None (0)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:44:02', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered 'No (N)'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-05T19:44:13', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '64466676-9a45-4f29-9be2-02457c3b8c6c' User entered '05 Aug 2020 19:44'	System	05 Aug 2020 23:44:16
	System	05 Aug 2020 23:44:16

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 3'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:28', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40'	System	07 Aug 2020 00:01:23
User entered 'None (0)'	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:31', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40'	System	07 Aug 2020 00:01:23
User entered 'None (0)'	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40'	System	07 Aug 2020 00:01:23
User entered 'None (0)'	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:51', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40' User entered 'None (0)'	System	07 Aug 2020 00:01:23
	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40'	System	07 Aug 2020 00:01:23
User entered 'None (0)'	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:00:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40' User entered 'None (0)'	System	07 Aug 2020 00:01:23
	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:01:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40'	System	07 Aug 2020 00:01:23
User entered 'No (N)'	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-06T20:01:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1cddfbf0-2e9f-44b8-9585-2717e1109c40'	System	07 Aug 2020 00:01:23
User entered '06 Aug 2020 20:01'	System	07 Aug 2020 00:01:23

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 4'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38'	System	07 Aug 2020 23:34:45
User entered 'None (0)'	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38'	System	07 Aug 2020 23:34:45
User entered 'None (0)'	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:13', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38'	System	07 Aug 2020 23:34:45
User entered 'None (0)'	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:16', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38' User entered 'None (0)'	System	07 Aug 2020 23:34:45
	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38'	System	07 Aug 2020 23:34:45
User entered 'None (0)'	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38'	System	07 Aug 2020 23:34:45
User entered 'None (0)'	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38' User entered 'No (N)'	System	07 Aug 2020 23:34:45
	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-07T19:34:41', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '659d9b4a-3daf-4717-87d5-76f2593f1d38'	System	07 Aug 2020 23:34:45
User entered '07 Aug 2020 19:34'	System	07 Aug 2020 23:34:45

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 5'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:34', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72' User entered 'None (0)'	System	08 Aug 2020 23:20:22
	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:37', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72' User entered 'None (0)'	System	08 Aug 2020 23:20:22
	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:40', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72' User entered 'None (0)'	System	08 Aug 2020 23:20:22
	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72' User entered 'None (0)'	System	08 Aug 2020 23:20:22
	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72' User entered 'None (0)'	System	08 Aug 2020 23:20:22
	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72' User entered 'None (0)'	System	08 Aug 2020 23:20:22
	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:19:53', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72'	System	08 Aug 2020 23:20:22
User entered 'No (N)'	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-08T19:20:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3d13dc23-232c-43b8-8adc-fb98ec64de72'	System	08 Aug 2020 23:20:22
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:22

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 6'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:30', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'None (0)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:32', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'None (0)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'None (0)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:38', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'None (0)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:41', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'None (0)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'None (0)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:27:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered 'No (N)'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-09T19:28:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cbfbedb8-ad12-436e-8c4b-a0e509d220c5' User entered '09 Aug 2020 19:28'	System	09 Aug 2020 23:28:01
	System	09 Aug 2020 23:28:01

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 7'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:30', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'None (0)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:34', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'None (0)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:37', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'None (0)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:39', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'None (0)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'None (0)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'None (0)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:30:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered 'No (N)'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-08-10T19:31:16', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f043f858-7c86-4140-801d-901e4e835176' User entered '10 Aug 2020 19:31'	System	10 Aug 2020 23:31:20
	System	10 Aug 2020 23:31:20

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:26:03

US3412118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:59:26

US3412118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:59:26

US3412118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:59:26

US3412118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:59:26

US3412118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:59:32

US3412118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'I'	System	14 Aug 2020 16:59:32

US3412118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 00:03:04

US3412118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 00:03:04

US3412118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 00:03:04

US3412118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 00:03:04

US3412118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 00:03:11

US3412118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User entered 'I'	System	19 Aug 2020 00:03:11

US3412118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:48:46

US3412118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:48:46

US3412118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:48:46

US3412118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:48:46

US3412118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:48:55

US3412118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User entered 'I'	System	01 Sep 2020 13:48:55

US3412118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:49:22

US3412118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:49:22

US3412118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Home (Home)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:49:22

US3412118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'VISIT2'	System	01 Sep 2020 13:49:22

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '01 Sep 2020'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:16'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '01 Sep 2020 09:16'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '36.6' C	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '80'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'bpm'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '16'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'breaths/min'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '128'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '84'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '01 Sep 2020'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '10:31'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '01 Sep 2020 10:31'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '98.6' F	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '76'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'bpm'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '15'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'breaths/min'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '122'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '85'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'mmHg'	System	21 Sep 2020 18:07:03

US3412118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:50

US3412118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '01 Sep 2020'	Jacob sekinger (b) (4)	21 Sep 2020 18:07:50

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:55'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '1 Sep 2020 09:55'	System	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'ONCE'	System	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 14:01:06

US3412118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:19

US3412118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '01 Sep 2020'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:19

US3412118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:24'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:19

US3412118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '01 Sep 2020 09:24'	System	21 Sep 2020 18:09:19

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '01 Sep 2020'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '09:27'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '01 Sep 2020 09:27'	System	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'No (N)'	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Jacob sekinger (b) (4)	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	21 Sep 2020 18:09:59

US3412118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	15 Sep 2020 15:21:16

US3412118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'I'	System	15 Sep 2020 15:21:16

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:32:46', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ed0f61f9-93f7-4405-b44f-2d3e10c115c2'	System	01 Sep 2020 14:33:09
User entered 'Yes (Y)'	System	01 Sep 2020 14:33:09

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:32:53', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ed0f61f9-93f7-4405-b44f-2d3e10c115c2'	System	01 Sep 2020 14:33:09
User entered '98.6'	System	01 Sep 2020 14:33:09

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:32:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ed0f61f9-93f7-4405-b44f-2d3e10c115c2'	System	01 Sep 2020 14:33:09
User entered 'No (N)'	System	01 Sep 2020 14:33:09

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ed0f61f9-93f7-4405-b44f-2d3e10c115c2'	System	01 Sep 2020 14:33:09
User entered '01 Sep 2020 10:33'	System	01 Sep 2020 14:33:09

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 10:15'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 12:45'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:02:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5f6891f9-8bfa-414b-b478-b3634ad46698' User entered 'Yes (Y)'	System	01 Sep 2020 23:03:12
	System	01 Sep 2020 23:03:12

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:02:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5f6891f9-8bfa-414b-b478-b3634ad46698' User entered '97.3'	System	01 Sep 2020 23:03:12
	System	01 Sep 2020 23:03:12

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5f6891f9-8bfa-414b-b478-b3634ad46698' User entered 'No (N)'	System	01 Sep 2020 23:03:12
	System	01 Sep 2020 23:03:12

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:08', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '5f6891f9-8bfa-414b-b478-b3634ad46698' User entered '01 Sep 2020 19:03'	System	01 Sep 2020 23:03:12
	System	01 Sep 2020 23:03:12

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 13:40'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 2'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:12:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3a7f5a88-a518-400c-9174-57c824a892a0' User entered 'Yes (Y)'	System	02 Sep 2020 23:13:15
	System	02 Sep 2020 23:13:15

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:12:55', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3a7f5a88-a518-400c-9174-57c824a892a0' User entered '98.3'	System	02 Sep 2020 23:13:15
	System	02 Sep 2020 23:13:15

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3a7f5a88-a518-400c-9174-57c824a892a0' User entered 'No (N)'	System	02 Sep 2020 23:13:15
	System	02 Sep 2020 23:13:15

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:11', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3a7f5a88-a518-400c-9174-57c824a892a0' User entered '02 Sep 2020 19:13'	System	02 Sep 2020 23:13:15
	System	02 Sep 2020 23:13:15

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 3'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a303043c-556a-4ebe-80fa-0d8a7e55a1e4' User entered 'Yes (Y)'	System	03 Sep 2020 23:04:38
	System	03 Sep 2020 23:04:38

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:28', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a303043c-556a-4ebe-80fa-0d8a7e55a1e4' User entered '98.4'	System	03 Sep 2020 23:04:38
	System	03 Sep 2020 23:04:38

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:32', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a303043c-556a-4ebe-80fa-0d8a7e55a1e4' User entered 'No (N)'	System	03 Sep 2020 23:04:38
	System	03 Sep 2020 23:04:38

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:36', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a303043c-556a-4ebe-80fa-0d8a7e55a1e4' User entered '03 Sep 2020 19:04'	System	03 Sep 2020 23:04:38
	System	03 Sep 2020 23:04:38

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 4'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:01:16', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd4730f96-57e9-4278-b8e6-f16a74e10c0e' User entered 'Yes (Y)'	System	04 Sep 2020 23:01:50
	System	04 Sep 2020 23:01:50

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:01:34', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd4730f96-57e9-4278-b8e6-f16a74e10c0e' User entered '97.4'	System	04 Sep 2020 23:01:50
	System	04 Sep 2020 23:01:50

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:01:41', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd4730f96-57e9-4278-b8e6-f16a74e10c0e' User entered 'No (N)'	System	04 Sep 2020 23:01:50
	System	04 Sep 2020 23:01:50

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:01:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd4730f96-57e9-4278-b8e6-f16a74e10c0e' User entered '04 Sep 2020 19:01'	System	04 Sep 2020 23:01:50
	System	04 Sep 2020 23:01:50

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 5'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:09:31', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3888fc55-0a7e-42e6-9bda-f0593f5a5b43' User entered 'Yes (Y)'	System	05 Sep 2020 23:10:03
	System	05 Sep 2020 23:10:03

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:09:48', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3888fc55-0a7e-42e6-9bda-f0593f5a5b43' User entered '98.2'	System	05 Sep 2020 23:10:03
	System	05 Sep 2020 23:10:03

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:09:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3888fc55-0a7e-42e6-9bda-f0593f5a5b43'	System	05 Sep 2020 23:10:03
User entered 'No (N)'	System	05 Sep 2020 23:10:03

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '3888fc55-0a7e-42e6-9bda-f0593f5a5b43'	System	05 Sep 2020 23:10:03
User entered '05 Sep 2020 19:10'	System	05 Sep 2020 23:10:03

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 6'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:18', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ac4c21b8-f41a-4fa3-9adc-89f26f4e1b3b' User entered 'Yes (Y)'	System	06 Sep 2020 23:53:46
	System	06 Sep 2020 23:53:46

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ac4c21b8-f41a-4fa3-9adc-89f26f4e1b3b' User entered '98.8'	System	06 Sep 2020 23:53:46
	System	06 Sep 2020 23:53:46

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:38', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ac4c21b8-f41a-4fa3-9adc-89f26f4e1b3b' User entered 'No (N)'	System	06 Sep 2020 23:53:46
	System	06 Sep 2020 23:53:46

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ac4c21b8-f41a-4fa3-9adc-89f26f4e1b3b'	System	06 Sep 2020 23:53:46
User entered '06 Sep 2020 19:53'	System	06 Sep 2020 23:53:46

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 7'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:11:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'df15c7ea-ae79-435c-94ec-7c02ac1c67d2'	System	07 Sep 2020 23:12:48
User entered 'Yes (Y)'	System	07 Sep 2020 23:12:48

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:12:27', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'df15c7ea-ae79-435c-94ec-7c02ac1c67d2'	System	07 Sep 2020 23:12:48
User entered '97.6'	System	07 Sep 2020 23:12:48

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:12:31', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'df15c7ea-ae79-435c-94ec-7c02ac1c67d2'	System	07 Sep 2020 23:12:48
User entered 'No (N)'	System	07 Sep 2020 23:12:48

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:12:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'df15c7ea-ae79-435c-94ec-7c02ac1c67d2'	System	07 Sep 2020 23:12:48
User entered '07 Sep 2020 19:12'	System	07 Sep 2020 23:12:48

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:09', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '26fa4f95-3127-4b04-84e1-b6e86a1d1690'	System	01 Sep 2020 14:33:29
User entered 'None (1)'	System	01 Sep 2020 14:33:29

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:12', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '26fa4f95-3127-4b04-84e1-b6e86a1d1690' User entered 'No (N)'	System	01 Sep 2020 14:33:29
	System	01 Sep 2020 14:33:29

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:15', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '26fa4f95-3127-4b04-84e1-b6e86a1d1690' User entered 'No (N)'	System	01 Sep 2020 14:33:29
	System	01 Sep 2020 14:33:29

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:19', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '26fa4f95-3127-4b04-84e1-b6e86a1d1690' User entered 'None (1)'	System	01 Sep 2020 14:33:29
	System	01 Sep 2020 14:33:29

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:27', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '26fa4f95-3127-4b04-84e1-b6e86a1d1690' User entered '01 Sep 2020 10:33'	System	01 Sep 2020 14:33:29
	System	01 Sep 2020 14:33:29

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 10:15'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 12:45'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ee2db93c-10d2-4bb6-ae2e-3fa004367f4c' User entered 'None (1)'	System	01 Sep 2020 23:03:59
	System	01 Sep 2020 23:03:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ee2db93c-10d2-4bb6-ae2e-3fa004367f4c' User entered 'No (N)'	System	01 Sep 2020 23:03:59
	System	01 Sep 2020 23:03:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ee2db93c-10d2-4bb6-ae2e-3fa004367f4c' User entered 'No (N)'	System	01 Sep 2020 23:03:59
	System	01 Sep 2020 23:03:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:50', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ee2db93c-10d2-4bb6-ae2e-3fa004367f4c' User entered 'None (1)'	System	01 Sep 2020 23:03:59
	System	01 Sep 2020 23:03:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:03:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ee2db93c-10d2-4bb6-ae2e-3fa004367f4c' User entered '01 Sep 2020 19:03'	System	01 Sep 2020 23:03:59
	System	01 Sep 2020 23:03:59

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 13:40'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 2'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:18', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '0ed3a8ac-5f92-4f25-aebd-76e129df751b' User entered 'None (1)'	System	02 Sep 2020 23:13:39
	System	02 Sep 2020 23:13:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '0ed3a8ac-5f92-4f25-aebd-76e129df751b' User entered 'No (N)'	System	02 Sep 2020 23:13:39
	System	02 Sep 2020 23:13:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:24', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '0ed3a8ac-5f92-4f25-aebd-76e129df751b' User entered 'No (N)'	System	02 Sep 2020 23:13:39
	System	02 Sep 2020 23:13:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '0ed3a8ac-5f92-4f25-aebd-76e129df751b' User entered 'None (1)'	System	02 Sep 2020 23:13:39
	System	02 Sep 2020 23:13:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '0ed3a8ac-5f92-4f25-aebd-76e129df751b'	System	02 Sep 2020 23:13:39
User entered '02 Sep 2020 19:13'	System	02 Sep 2020 23:13:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 3'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '17b18e51-0660-4e8d-8592-af7af8f4ac68'	System	03 Sep 2020 23:05:09
User entered 'None (1)'	System	03 Sep 2020 23:05:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:46', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '17b18e51-0660-4e8d-8592-af7af8f4ac68' User entered 'No (N)'	System	03 Sep 2020 23:05:09
	System	03 Sep 2020 23:05:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '17b18e51-0660-4e8d-8592-af7af8f4ac68' User entered 'No (N)'	System	03 Sep 2020 23:05:09
	System	03 Sep 2020 23:05:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:04:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '17b18e51-0660-4e8d-8592-af7af8f4ac68' User entered 'None (1)'	System	03 Sep 2020 23:05:09
	System	03 Sep 2020 23:05:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:04', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '17b18e51-0660-4e8d-8592-af7af8f4ac68'	System	03 Sep 2020 23:05:09
User entered '03 Sep 2020 19:05'	System	03 Sep 2020 23:05:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 4'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a486a053-dd4b-4392-9dd9-502a2cd31329'	System	04 Sep 2020 23:02:39
User entered 'None (1)'	System	04 Sep 2020 23:02:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:06', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a486a053-dd4b-4392-9dd9-502a2cd31329' User entered 'No (N)'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:19', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a486a053-dd4b-4392-9dd9-502a2cd31329' User entered 'No (N)'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a486a053-dd4b-4392-9dd9-502a2cd31329' User entered 'None (1)'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:38', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a486a053-dd4b-4392-9dd9-502a2cd31329' User entered '04 Sep 2020 19:02'	System	04 Sep 2020 23:02:39
	System	04 Sep 2020 23:02:39

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 5'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:13', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e71abaff-e902-4343-9baa-5771a410b565'	System	05 Sep 2020 23:10:53
User entered 'None (1)'	System	05 Sep 2020 23:10:53

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e71abaff-e902-4343-9baa-5771a410b565' User entered 'No (N)'	System	05 Sep 2020 23:10:53
	System	05 Sep 2020 23:10:53

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:40', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e71abaff-e902-4343-9baa-5771a410b565' User entered 'No (N)'	System	05 Sep 2020 23:10:53
	System	05 Sep 2020 23:10:53

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:44', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e71abaff-e902-4343-9baa-5771a410b565' User entered 'None (1)'	System	05 Sep 2020 23:10:53
	System	05 Sep 2020 23:10:53

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:51', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'e71abaff-e902-4343-9baa-5771a410b565'	System	05 Sep 2020 23:10:53
User entered '05 Sep 2020 19:10'	System	05 Sep 2020 23:10:53

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 6'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '325702e5-21da-44b8-8e01-dea11ebdd104' User entered 'None (1)'	System	06 Sep 2020 23:54:09
	System	06 Sep 2020 23:54:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:53', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '325702e5-21da-44b8-8e01-dea11ebdd104' User entered 'No (N)'	System	06 Sep 2020 23:54:09
	System	06 Sep 2020 23:54:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '325702e5-21da-44b8-8e01-dea11ebdd104' User entered 'No (N)'	System	06 Sep 2020 23:54:09
	System	06 Sep 2020 23:54:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:53:59', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '325702e5-21da-44b8-8e01-dea11ebdd104' User entered 'None (1)'	System	06 Sep 2020 23:54:09
	System	06 Sep 2020 23:54:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:07', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '325702e5-21da-44b8-8e01-dea11ebdd104' User entered '06 Sep 2020 19:54'	System	06 Sep 2020 23:54:09
	System	06 Sep 2020 23:54:09

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 7'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:12:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '28a4f235-43d2-4db2-a7e4-98ca99ebb8b2' User entered 'None (1)'	System	07 Sep 2020 23:13:19
	System	07 Sep 2020 23:13:19

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:12:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '28a4f235-43d2-4db2-a7e4-98ca99ebb8b2' User entered 'No (N)'	System	07 Sep 2020 23:13:19
	System	07 Sep 2020 23:13:19

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:12:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '28a4f235-43d2-4db2-a7e4-98ca99ebb8b2' User entered 'No (N)'	System	07 Sep 2020 23:13:19
	System	07 Sep 2020 23:13:19

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '28a4f235-43d2-4db2-a7e4-98ca99ebb8b2' User entered 'None (1)'	System	07 Sep 2020 23:13:19
	System	07 Sep 2020 23:13:19

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:16', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '28a4f235-43d2-4db2-a7e4-98ca99ebb8b2' User entered '07 Sep 2020 19:13'	System	07 Sep 2020 23:13:19
	System	07 Sep 2020 23:13:19

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:32', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered 'None (0)'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:36', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered 'None (0)'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:39', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered 'None (0)'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered 'None (0)'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered 'None (0)'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered 'None (0)'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:33:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75'	System	01 Sep 2020 14:34:01
User entered 'No (N)'	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T10:34:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2e443a8d-ee92-4fb0-ab0b-81d1e6f88e75' User entered '01 Sep 2020 10:34'	System	01 Sep 2020 14:34:01
	System	01 Sep 2020 14:34:01

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 10:15'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 12:45'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'None (0)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:04', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'None (0)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:09', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'None (0)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:14', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'None (0)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'None (0)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:19', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'None (0)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc' User entered 'No (N)'	System	01 Sep 2020 23:04:27
	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-01T19:04:26', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e62c4f1-514a-4d32-9a4d-6d7f7444f1dc'	System	01 Sep 2020 23:04:27
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 23:04:27

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '01 Sep 2020 13:40'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 2'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'None (0)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'None (0)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:48', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'None (0)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'None (0)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'None (0)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:13:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'None (0)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:14:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4' User entered 'No (N)'	System	02 Sep 2020 23:14:13
	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-02T19:14:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'cf85a308-82ac-4547-94c7-5a6ebb5bfed4'	System	02 Sep 2020 23:14:13
User entered '02 Sep 2020 19:14'	System	02 Sep 2020 23:14:13

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 3'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:09', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'None (0)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:12', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'None (0)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:15', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'None (0)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'None (0)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'None (0)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'None (0)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:27', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered 'No (N)'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-03T19:05:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd3a89845-d2c2-46cf-afe9-e84b7ffb0134' User entered '03 Sep 2020 19:05'	System	03 Sep 2020 23:05:42
	System	03 Sep 2020 23:05:42

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 4'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'None (0)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:50', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'None (0)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'None (0)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:02:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'None (0)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:03:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'None (0)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:03:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'None (0)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:03:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063' User entered 'No (N)'	System	04 Sep 2020 23:03:23
	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-04T19:03:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '54249e29-3e37-4916-ac51-420566e17063'	System	04 Sep 2020 23:03:23
User entered '04 Sep 2020 19:03'	System	04 Sep 2020 23:03:23

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 5'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'None (0)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:10:59', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'None (0)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:11:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'None (0)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:11:06', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'None (0)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:11:10', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'None (0)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:11:14', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'None (0)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:11:18', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered 'No (N)'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-05T19:11:27', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2823af08-5d9e-4721-babd-5ac13b2766a8' User entered '05 Sep 2020 19:11'	System	05 Sep 2020 23:11:29
	System	05 Sep 2020 23:11:29

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 6'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:15', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'None (0)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'None (0)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'None (0)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:24', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'None (0)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:26', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'None (0)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:32', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'None (0)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered 'No (N)'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-06T19:54:46', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '88ac4e3c-cdd9-4fb9-a2d6-8b50d6aa55e4' User entered '06 Sep 2020 19:54'	System	06 Sep 2020 23:54:48
	System	06 Sep 2020 23:54:48

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	01 Sep 2020 14:01:06
User entered 'Day 7'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'None (0)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:24', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'None (0)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:33', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'None (0)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:36', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'None (0)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:40', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'None (0)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'None (0)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:48', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c' User entered 'No (N)'	System	07 Sep 2020 23:14:02
	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-09-07T19:13:59', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'c35e45f3-5bec-4ab8-a403-dd551a8fa27c'	System	07 Sep 2020 23:14:02
User entered '07 Sep 2020 19:13'	System	07 Sep 2020 23:14:02

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:01:06

US3412118

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:01:06

US3412118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	15 Sep 2020 15:21:36

US3412118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered '8 Sep 2020'	Mason Urban (b) (4)	15 Sep 2020 15:21:36

US3412118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	15 Sep 2020 15:21:36

US3412118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered empty.	Mason Urban (b) (4)	15 Sep 2020 15:21:36

US3412118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:48:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	15 Sep 2020 15:21:41

US3412118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User entered 'I'	System	15 Sep 2020 15:21:41

US3412118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:33
User entered 'Yes (Y)'	Mason Urban (b) (4)	15 Sep 2020 15:26:29

US3412118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:33
User entered '15 Sep 2020'	Mason Urban (b) (4)	15 Sep 2020 15:26:29

US3412118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:33
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	15 Sep 2020 15:26:29

US3412118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:33
User entered empty.	Mason Urban (b) (4)	15 Sep 2020 15:26:29

US3412118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:33
User entered 'Yes (Y)'	Mason Urban (b) (4)	15 Sep 2020 15:26:42

US3412118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User entered 'I'	System	15 Sep 2020 15:26:42

US3412118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Sep 2020 16:06:59

US3412118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '23 Sep 2020'	Mason Urban (b) (4)	23 Sep 2020 16:06:59

US3412118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Sep 2020 16:06:59

US3412118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Mason Urban (b) (4)	23 Sep 2020 16:06:59

US3412118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Sep 2020 16:07:04

US3412118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:31
User entered 'I'	System	23 Sep 2020 16:07:04

US3412118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 13:52:58
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'UPDATED SAMPLE DATA MISSING IN EDC' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 17:08:28
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:14:20
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	29 Sep 2020 12:57:39

US3412118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '29 Sep 2020'	Steven Anderson (b) (4)	29 Sep 2020 12:57:39

US3412118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	29 Sep 2020 12:57:39

US3412118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'VISIT3'	System	29 Sep 2020 12:57:39

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'No (N)'	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty.	Steven Anderson (b) (4)	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered empty.	System	29 Sep 2020 12:57:49

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39

US3412118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39

US3412118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Dec 2020 14:55:56
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Sep 2020 12:58:03

US3412118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	28 Dec 2020 14:55:56
User entered '29 Sep 2020'	Steven Anderson (b) (4)	29 Sep 2020 12:58:03

US3412118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Sep 2020 12:58:22

US3412118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '29 Sep 2020'	Steven Anderson (b) (4)	29 Sep 2020 12:58:22

US3412118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User entered '08:24'	Steven Anderson (b) (4)	29 Sep 2020 12:58:22

US3412118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered '29 Sep 2020 08:24'	System	29 Sep 2020 12:58:22

US3412118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:36:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 04:43:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED SALIVA LOG DAY 3' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 17:06:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:50:22
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	29 Sep 2020 12:58:28

US3412118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'I'	System	29 Sep 2020 12:58:28

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 64'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-05T13:21:25', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd2f872fa-ded8-4278-a540-7c30fb4bc4bf'	System	05 Oct 2020 17:21:51
User entered 'No (N)'	System	05 Oct 2020 17:21:51

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-05T13:20:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd2f872fa-ded8-4278-a540-7c30fb4bc4bf'	System	05 Oct 2020 17:21:51
User entered 'No (N)'	System	05 Oct 2020 17:21:51

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-05T13:21:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd2f872fa-ded8-4278-a540-7c30fb4bc4bf' User entered '05 Oct 2020 13:21:49'	System	05 Oct 2020 17:21:51
	System	05 Oct 2020 17:21:51

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 71'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-13T12:14:09', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '969aec24-2084-4e37-89f7-b1741003a370' User entered 'No (N)'	System	13 Oct 2020 16:14:36
	System	13 Oct 2020 16:14:36

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-13T12:14:15', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '969aec24-2084-4e37-89f7-b1741003a370'	System	13 Oct 2020 16:14:36
User entered 'No (N)'	System	13 Oct 2020 16:14:36

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-13T12:14:31', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '969aec24-2084-4e37-89f7-b1741003a370' User entered '13 Oct 2020 12:14:31'	System	13 Oct 2020 16:14:36
	System	13 Oct 2020 16:14:36

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 78'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-19T11:49:37', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'b8739959-cd0b-474f-bfc6-1143c526c276'	System	19 Oct 2020 15:49:59
User entered 'No (N)'	System	19 Oct 2020 15:49:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-19T11:49:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'b8739959-cd0b-474f-bfc6-1143c526c276'	System	19 Oct 2020 15:49:59
User entered 'No (N)'	System	19 Oct 2020 15:49:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-10-19T11:49:53', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'b8739959-cd0b-474f-bfc6-1143c526c276' User entered '19 Oct 2020 11:49:53'	System	19 Oct 2020 15:49:59
	System	19 Oct 2020 15:49:59

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 92'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-04T19:28:46', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a1aa9d80-38e9-4804-bb81-1fd76ec9e460'	System	05 Nov 2020 00:29:02
User entered 'No (N)'	System	05 Nov 2020 00:29:02

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-04T19:28:50', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a1aa9d80-38e9-4804-bb81-1fd76ec9e460'	System	05 Nov 2020 00:29:02
User entered 'No (N)'	System	05 Nov 2020 00:29:02

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-04T19:28:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'a1aa9d80-38e9-4804-bb81-1fd76ec9e460'	System	05 Nov 2020 00:29:02
User entered '04 Nov 2020 19:28:58'	System	05 Nov 2020 00:29:02

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 99'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-11T16:32:08', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf67a40d-8ae4-48ea-bf29-6c777c99be65'	System	11 Nov 2020 21:32:33
User entered 'No (N)'	System	11 Nov 2020 21:32:33

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-11T16:32:14', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf67a40d-8ae4-48ea-bf29-6c777c99be65'	System	11 Nov 2020 21:32:33
User entered 'No (N)'	System	11 Nov 2020 21:32:33

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-11T16:32:30', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'bf67a40d-8ae4-48ea-bf29-6c777c99be65'	System	11 Nov 2020 21:32:33
User entered '11 Nov 2020 16:32:30'	System	11 Nov 2020 21:32:33

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered 'Day 106'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-17T14:07:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '197dfb96-b72c-4f2f-a0b5-061569b19d83'	System	17 Nov 2020 19:08:11
User entered 'No (N)'	System	17 Nov 2020 19:08:11

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-17T14:07:59', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '197dfb96-b72c-4f2f-a0b5-061569b19d83'	System	17 Nov 2020 19:08:11
User entered 'No (N)'	System	17 Nov 2020 19:08:11

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-17T14:08:08', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '197dfb96-b72c-4f2f-a0b5-061569b19d83'	System	17 Nov 2020 19:08:11
User entered '17 Nov 2020 14:08:08'	System	17 Nov 2020 19:08:11

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 14:26:03

US3412118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:12
Data entry locked.	System	04 Aug 2020 14:26:03
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 14:26:03

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-23T12:42:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67518fa0-609a-4375-9afb-a3f4f7aa04bc' User entered 'No (N)'	System	23 Nov 2020 17:43:46

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-23T12:43:03', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67518fa0-609a-4375-9afb-a3f4f7aa04bc' User entered 'No (N)'	System	23 Nov 2020 17:43:46

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-23T12:43:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '67518fa0-609a-4375-9afb-a3f4f7aa04bc' User entered '23 Nov 2020 12:43:43'	System	23 Nov 2020 17:43:46
	System	23 Nov 2020 17:43:46

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-29T18:04:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd7245ea2-d919-40a8-9459-a13c48d308fe' User entered 'No (N)'	System	29 Nov 2020 23:04:23
	System	29 Nov 2020 23:04:23

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-29T18:04:11', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd7245ea2-d919-40a8-9459-a13c48d308fe' User entered 'No (N)'	System	29 Nov 2020 23:04:23

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-11-29T18:04:20', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'd7245ea2-d919-40a8-9459-a13c48d308fe' User entered '29 Nov 2020 18:04:20'	System	29 Nov 2020 23:04:23
	System	29 Nov 2020 23:04:23

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-05T14:10:28', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '92139b66-f5c0-4b54-935d-a8878f9ee60c' User entered 'Yes (Y)'	System	05 Dec 2020 19:11:10
	System	05 Dec 2020 19:11:10

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-05T14:10:34', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '92139b66-f5c0-4b54-935d-a8878f9ee60c' User entered 'Yes (Y)'	System	05 Dec 2020 19:11:10
	System	05 Dec 2020 19:11:10

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Please 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-05T14:10:45', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '92139b66-f5c0-4b54-935d-a8878f9ee60c'	System	05 Dec 2020 19:11:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 19:11:10

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-05T14:10:51', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '92139b66-f5c0-4b54-935d-a8878f9ee60c' User entered 'No (N)'	System	05 Dec 2020 19:11:10
	System	05 Dec 2020 19:11:10

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-05T14:10:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '92139b66-f5c0-4b54-935d-a8878f9ee60c' User entered 'No (N)'	System	05 Dec 2020 19:11:10
	System	05 Dec 2020 19:11:10

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-05T14:11:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '92139b66-f5c0-4b54-935d-a8878f9ee60c' User entered '05 Dec 2020 14:11:01'	System	05 Dec 2020 19:11:10
	System	05 Dec 2020 19:11:10

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-11T19:01:18', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '894769fb-427b-4eff-b5bb-10d13991d4a2' User entered 'No (N)'	System	12 Dec 2020 00:01:28
	System	12 Dec 2020 00:01:28

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-11T19:01:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '894769fb-427b-4eff-b5bb-10d13991d4a2'	System	12 Dec 2020 00:01:28
User entered 'No (N)'	System	12 Dec 2020 00:01:28

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-11T19:01:25', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '894769fb-427b-4eff-b5bb-10d13991d4a2' User entered '11 Dec 2020 19:01:25'	System	12 Dec 2020 00:01:28
	System	12 Dec 2020 00:01:28

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-19T12:09:25', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e531bcf-632e-48ef-a398-2a48afed4c4e' User entered 'No (N)'	System	19 Dec 2020 17:09:43
	System	19 Dec 2020 17:09:43

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-19T12:09:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e531bcf-632e-48ef-a398-2a48afed4c4e' User entered 'No (N)'	System	19 Dec 2020 17:09:43
	System	19 Dec 2020 17:09:43

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-19T12:09:38', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '7e531bcf-632e-48ef-a398-2a48afed4c4e' User entered '19 Dec 2020 12:09:38'	System	19 Dec 2020 17:09:43
	System	19 Dec 2020 17:09:43

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-26T18:06:28', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '376c8424-15ea-4ba0-9220-e8b2ed684b2e' User entered 'No (N)'	System	26 Dec 2020 23:06:43
	System	26 Dec 2020 23:06:43

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-26T18:06:32', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '376c8424-15ea-4ba0-9220-e8b2ed684b2e' User entered 'No (N)'	System	26 Dec 2020 23:06:43
	System	26 Dec 2020 23:06:43

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2020-12-26T18:06:41', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '376c8424-15ea-4ba0-9220-e8b2ed684b2e' User entered '26 Dec 2020 18:06:41'	System	26 Dec 2020 23:06:43
	System	26 Dec 2020 23:06:43

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-02T12:19:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '80a908dd-66c0-4505-bce1-9ec5d4a7a98b'	System	02 Jan 2021 17:19:31
User entered 'No (N)'	System	02 Jan 2021 17:19:31

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-02T12:19:25', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '80a908dd-66c0-4505-bce1-9ec5d4a7a98b' User entered 'No (N)'	System	02 Jan 2021 17:19:31
	System	02 Jan 2021 17:19:31

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-02T12:19:29', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '80a908dd-66c0-4505-bce1-9ec5d4a7a98b' User entered '02 Jan 2021 12:19:29'	System	02 Jan 2021 17:19:31
	System	02 Jan 2021 17:19:31

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-08T14:13:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f27b71f3-4c88-4a31-80ca-7ef077885cae' User entered 'No (N)'	System	08 Jan 2021 19:13:59
	System	08 Jan 2021 19:13:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-08T14:13:50', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f27b71f3-4c88-4a31-80ca-7ef077885cae' User entered 'No (N)'	System	08 Jan 2021 19:13:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-08T14:13:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'f27b71f3-4c88-4a31-80ca-7ef077885cae' User entered '08 Jan 2021 14:13:56'	System	08 Jan 2021 19:13:59
	System	08 Jan 2021 19:13:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-14T16:27:43', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2585e788-c922-4d1e-960b-fdd9ce8b1c6b' User entered 'No (N)'	System	14 Jan 2021 21:27:57

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-14T16:27:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2585e788-c922-4d1e-960b-fdd9ce8b1c6b' User entered 'No (N)'	System	14 Jan 2021 21:27:57

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-01-14T16:27:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '2585e788-c922-4d1e-960b-fdd9ce8b1c6b' User entered '14 Jan 2021 16:27:52'	System	14 Jan 2021 21:27:57
	System	14 Jan 2021 21:27:57

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-08T07:47:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '6fa7833c-bc59-4497-b4c2-38e4321d7232'	System	08 Feb 2021 12:48:05
User entered 'No (N)'	System	08 Feb 2021 12:48:05

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-08T07:47:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '6fa7833c-bc59-4497-b4c2-38e4321d7232'	System	08 Feb 2021 12:48:05
User entered 'No (N)'	System	08 Feb 2021 12:48:05

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-08T07:48:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '6fa7833c-bc59-4497-b4c2-38e4321d7232' User entered '08 Feb 2021 07:48:01'	System	08 Feb 2021 12:48:05
	System	08 Feb 2021 12:48:05

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-15T08:52:19', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ce6f47c1-5ffd-42a3-a19f-48eb4727cace' User entered 'No (N)'	System	15 Feb 2021 13:52:29

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-15T08:52:23', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ce6f47c1-5ffd-42a3-a19f-48eb4727cace' User entered 'No (N)'	System	15 Feb 2021 13:52:29

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-15T08:52:26', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'ce6f47c1-5ffd-42a3-a19f-48eb4727cace' User entered '15 Feb 2021 08:52:26'	System	15 Feb 2021 13:52:29
	System	15 Feb 2021 13:52:29

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-22T08:21:32', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'fd6c1868-8f84-421e-8669-b77bda3d9db5' User entered 'No (N)'	System	22 Feb 2021 13:21:47
	System	22 Feb 2021 13:21:47

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-22T08:21:35', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'fd6c1868-8f84-421e-8669-b77bda3d9db5' User entered 'No (N)'	System	22 Feb 2021 13:21:47
	System	22 Feb 2021 13:21:47

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-22T08:21:41', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'fd6c1868-8f84-421e-8669-b77bda3d9db5' User entered '22 Feb 2021 08:21:41'	System	22 Feb 2021 13:21:47
	System	22 Feb 2021 13:21:47

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-26T10:42:14', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1ed6bc69-9fd4-45c2-ae8d-507a9a4e1f4e' User entered 'No (N)'	System	26 Feb 2021 15:42:24

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-26T10:42:17', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1ed6bc69-9fd4-45c2-ae8d-507a9a4e1f4e' User entered 'No (N)'	System	26 Feb 2021 15:42:24

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-02-26T10:42:21', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1ed6bc69-9fd4-45c2-ae8d-507a9a4e1f4e' User entered '26 Feb 2021 10:42:21'	System	26 Feb 2021 15:42:24
	System	26 Feb 2021 15:42:24

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-07T15:52:33', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '42919d42-0f36-4eee-a5ca-091390191ffb' User entered 'No (N)'	System	07 Mar 2021 20:52:52

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-07T15:52:41', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '42919d42-0f36-4eee-a5ca-091390191ffb' User entered 'No (N)'	System	07 Mar 2021 20:52:52

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-07T15:52:49', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '42919d42-0f36-4eee-a5ca-091390191ffb' User entered '07 Mar 2021 15:52:49'	System	07 Mar 2021 20:52:52
	System	07 Mar 2021 20:52:52

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-12T19:52:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '9ef687d2-08df-43ed-a22a-6430e4405f46'	System	13 Mar 2021 00:53:08
User entered 'No (N)'	System	13 Mar 2021 00:53:08

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-12T19:52:59', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '9ef687d2-08df-43ed-a22a-6430e4405f46'	System	13 Mar 2021 00:53:08
User entered 'No (N)'	System	13 Mar 2021 00:53:08

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-12T19:53:05', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '9ef687d2-08df-43ed-a22a-6430e4405f46' User entered '12 Mar 2021 19:53:05'	System	13 Mar 2021 00:53:08
	System	13 Mar 2021 00:53:08

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-18T10:43:19', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '210f0a31-d8c0-4459-b1c9-ad7a88ecd6b9'	System	18 Mar 2021 14:43:31
User entered 'No (N)'	System	18 Mar 2021 14:43:31

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-18T10:43:22', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '210f0a31-d8c0-4459-b1c9-ad7a88ecd6b9' User entered 'No (N)'	System	18 Mar 2021 14:43:31
	System	18 Mar 2021 14:43:31

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-18T10:43:26', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '210f0a31-d8c0-4459-b1c9-ad7a88ecd6b9' User entered '18 Mar 2021 10:43:26'	System	18 Mar 2021 14:43:31
	System	18 Mar 2021 14:43:31

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-02T20:01:24', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dce05ee0-493d-488d-9136-e8eb638c1ed2' User entered 'No (N)'	System	09 Apr 2021 23:55:55
	System	09 Apr 2021 23:55:55

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-02T20:01:31', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dce05ee0-493d-488d-9136-e8eb638c1ed2'	System	09 Apr 2021 23:55:55
User entered 'No (N)'	System	09 Apr 2021 23:55:55

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-02T20:01:54', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'dce05ee0-493d-488d-9136-e8eb638c1ed2' User entered '02 Apr 2021 20:01:54'	System	09 Apr 2021 23:55:55
	System	09 Apr 2021 23:55:55

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-09T19:55:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '4b5d766e-d175-47e7-81ce-782c90595ad6'	System	09 Apr 2021 23:56:02
User entered 'No (N)'	System	09 Apr 2021 23:56:02

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-09T19:55:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '4b5d766e-d175-47e7-81ce-782c90595ad6'	System	09 Apr 2021 23:56:02
User entered 'No (N)'	System	09 Apr 2021 23:56:02

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-09T19:56:00', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '4b5d766e-d175-47e7-81ce-782c90595ad6'	System	09 Apr 2021 23:56:02
User entered '09 Apr 2021 19:56:00'	System	09 Apr 2021 23:56:02

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-16T20:14:42', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1e6accaf-6a61-4496-b1f5-95b3c9dc6f29' User entered 'No (N)'	System	17 Apr 2021 00:15:01
	System	17 Apr 2021 00:15:01

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-16T20:14:50', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1e6accaf-6a61-4496-b1f5-95b3c9dc6f29'	System	17 Apr 2021 00:15:01
User entered 'No (N)'	System	17 Apr 2021 00:15:01

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-16T20:14:58', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '1e6accaf-6a61-4496-b1f5-95b3c9dc6f29'	System	17 Apr 2021 00:15:01
User entered '16 Apr 2021 20:14:58'	System	17 Apr 2021 00:15:01

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-24T12:13:48', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '76ab4b0d-8377-428f-9a4c-baec7ef2b7be'	System	24 Apr 2021 16:13:59
User entered 'No (N)'	System	24 Apr 2021 16:13:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-24T12:13:51', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '76ab4b0d-8377-428f-9a4c-baec7ef2b7be' User entered 'No (N)'	System	24 Apr 2021 16:13:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-04-24T12:13:56', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: '76ab4b0d-8377-428f-9a4c-baec7ef2b7be' User entered '24 Apr 2021 12:13:56'	System	24 Apr 2021 16:13:59
	System	24 Apr 2021 16:13:59

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-05-02T00:08:47', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'fc15e0c0-c7ec-4418-83ed-ed5541f1e687'	System	02 May 2021 04:09:00
User entered 'No (N)'	System	02 May 2021 04:09:00

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

Have you been exposed to someone with 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 (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-05-02T00:08:52', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'fc15e0c0-c7ec-4418-83ed-ed5541f1e687'	System	02 May 2021 04:09:00
User entered 'No (N)'	System	02 May 2021 04:09:00

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-05-02T00:08:57', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'fc15e0c0-c7ec-4418-83ed-ed5541f1e687'	System	02 May 2021 04:09:00
User entered '02 May 2021 00:08:57'	System	02 May 2021 04:09:00

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:18:54

US3412118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:18:54
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:18:54

US3412118

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:51:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-03T09:54:38', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'edc901c0-85ae-4425-b9e2-ad38ada77502' User entered 'No (N)'	System	03 Mar 2021 14:55:07
	System	03 Mar 2021 14:55:07

US3412118

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:51:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (43F0DE7D-05B7-48AD-A257-56B9B4693E40)', Time: '2021-03-03T09:55:01', User OID: 'PatientReportedOutcome (US3412118)', ODM File OID: 'edc901c0-85ae-4425-b9e2-ad38ada77502' User entered '03 Mar 2021 09:55:01'	System	03 Mar 2021 14:55:07
	System	03 Mar 2021 14:55:07

US3412118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	27 Oct 2020 14:34:40

US3412118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered '27 Oct 2020'	Mason Urban (b) (4)	27 Oct 2020 14:34:40

US3412118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	27 Oct 2020 14:34:40

US3412118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered empty.	Mason Urban (b) (4)	27 Oct 2020 14:34:40

US3412118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	27 Oct 2020 14:34:44

US3412118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:22:39
User entered 'I'	System	27 Oct 2020 14:34:44

US3412118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Nov 2020 21:02:52

US3412118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 01-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 01-DEC-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 10:01:47
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 01-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 01-DEC-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify. ' answered with 'UPDATED ALL INFORMATION' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:29:35
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 01-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, corresponding swab sample is missing in EDC for 01-DEC-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form, else clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 11:27:29
User entered '30 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	30 Nov 2020 21:02:52

US3412118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4)	30 Nov 2020 21:02:52

US3412118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Jacob sekinger (b) (4)	30 Nov 2020 21:02:52

US3412118

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Nov 2020 21:02:59

US3412118

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User entered 'I'	System	30 Nov 2020 21:02:59

US3412118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	30 Dec 2020 16:48:33

US3412118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '30 Dec 2020'	Mason Urban (b) (4)	30 Dec 2020 16:48:33

US3412118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	30 Dec 2020 16:48:33

US3412118

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Mason Urban (b) (4)	30 Dec 2020 16:48:33

US3412118

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	30 Dec 2020 16:48:17

US3412118

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User entered 'I'	System	30 Dec 2020 16:48:17

US3412118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Jan 2021 16:07:56

US3412118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '29 Jan 2021'	Mason Urban (b) (4)	29 Jan 2021 16:07:56

US3412118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Jan 2021 16:07:56

US3412118

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Mason Urban (b) (4)	29 Jan 2021 16:07:56

US3412118

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Jan 2021 16:08:00

US3412118

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:36:49
User entered 'I'	System	29 Jan 2021 16:08:00

US3412118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 15:58:29

US3412118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	03 Mar 2021 15:58:29

US3412118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[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 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	03 Mar 2021 15:58:29

US3412118

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'VISIT4'	System	03 Mar 2021 15:58:29

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '09:08'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '03 Mar 2021 09:08'	System	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '97.3' F	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '77'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'bpm'	System	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '20'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'breaths/min'	System	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '150'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'mmHg'	System	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '92'	Andrea Newlands (b) (4)	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'mmHg'	System	30 Mar 2021 14:19:35

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38

US3412118

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38

US3412118

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'No (N)'	Andrea Newlands (b) (4)	03 Mar 2021 16:00:21

US3412118

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Andrea Newlands (b) (4)	03 Mar 2021 16:00:21

US3412118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 16:00:51

US3412118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	03 Mar 2021 16:00:51

US3412118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '09:30'	Andrea Newlands (b) (4)	03 Mar 2021 16:00:51

US3412118

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered '03 Mar 2021 09:30'	System	03 Mar 2021 16:00:51

US3412118

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 16:01:15

US3412118

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:07:38
User entered 'I'	System	03 Mar 2021 16:01:15

US3412118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:55:29

US3412118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:55:29

US3412118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:55:29

US3412118

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'FULL MAILBOX 30 MAR 2021. Contact Made 31 MAR 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:53:31
User entered 'Full Mailbox 30 MAR 2021.'		30 Mar 2021 20:55:29

US3412118

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:53:34

US3412118

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 15:53:34

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:52

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:19:55
User entered '1 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:02:52

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:52

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:19:55
User entered '11:00'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:02:52

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:52

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:01
User entered '1 Dec 2020 11:00'	System	28 Dec 2020 15:02:52

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:52

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:19:55
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:03:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 15:03:00
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:03:00
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:02:52
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:02:52

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:52

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:19:55
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:02:52

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '30 Nov 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered missing code ND - Not Done.	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User entered '%'	System	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Dec 2020 15:05:56
User entered '36.6' C	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:31:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:04:32

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '1 Dec 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered missing code ND - Not Done.	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:05:26

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User entered '%'	System	28 Dec 2020 15:05:26

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '36.6' C	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:05:26

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	28 Dec 2020 15:07:53
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	28 Dec 2020 15:07:53
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:31:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 15:07:53
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:05:26
	(b) (4)	

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Day 3 (Day 3)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '2 Dec 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '97'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User entered '%'	System	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '98.2' F	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:13
User closed query 'Then please enter NOT DONE' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 13:09:36
Query 'Then please enter NOT DONE' answered with 'information has been updated' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:16:34
Signature has been broken.		19 Apr 2021 18:15:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		19 Apr 2021 18:15:51
User opened query 'Then please enter NOT DONE' (Site from CRA).		19 Apr 2021 15:06:23
User closed query 'Please complete. Thank you!' (Site from CRA).		19 Apr 2021 15:06:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
Query 'Please complete. Thank you!' answered with 'information is unknown as this was completed by the subject' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 20:20:23
User opened query 'Please complete. Thank you!' (Site from CRA).	(b) (4)	19 Mar 2021 13:05:18
User entered empty.		28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:31:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:11:01

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '3 Dec 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '97'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User entered '%'	System	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '98.3' F	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:31:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:12:06

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Day 5 (Day 5)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '4 Dec 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered missing code ND - Not Done.	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User entered '%'	System	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered missing code ND - Not Done.	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'None (None)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:31:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:13:49

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered '1 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered '1 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:21:39
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:31:52

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:19
User entered '0'	System	28 Dec 2020 15:14:24

US3412118

Folder: Covid-19 Assessment 01 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:31:52

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Dec 2020 15:14:31

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 3 is dated 03DEC2020 in EDC, however the same is dated as 09DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 06:17:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 3 is dated 03DEC2020 in EDC, however the same is dated as 09DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks' answered with 'this has been updated in PPD portal to 03-Dec-20 which is the correct draw date' (Site from DM).	Steven Anderson (b) (4) (b) (4)	14 Apr 2021 13:27:17
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 3 is dated 03DEC2020 in EDC, however the same is dated as 09DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:26:09
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the sample collected is valid, if yes, has it been sent to lab, kindly provide with accession number and tracking details for reference.Thanks' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:17:27
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the sample collected is valid, if yes, has it been sent to lab, kindly provide with accession number and tracking details for reference.Thanks' answered with 'Sample was collected accession number 1F651305640' (Site from DM).		31 Mar 2021 20:24:49
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the sample collected is valid, if yes, has it been sent to lab, kindly provide with accession number and tracking details for reference.Thanks' (Site from DM).		05 Feb 2021 07:18:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		05 Feb 2021 07:18:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with '09-Dec-2020 was the date the subject returned the lab to the site. 03-dec-2020 is the date that the subject spat in the tube and collected the sample' (Site from DM).	Steven Anderson (b) (4)	26 Jan 2021 14:20:14
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 04:43:47

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:19:49
	(b) (4)	

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:19:49
	(b) (4)	

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:19:49
	(b) (4)	

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:19:49
	(b) (4)	

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:19:49
	(b) (4)	

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:31:52

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:31:52

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:19:49

US3412118

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:19:49
	(b) (4)	

US3412118

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 14:59:39

US3412118

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '1 Dec 2020'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 14:59:39

US3412118

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	28 Dec 2020 14:59:39

US3412118

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User entered 'SICKD1'	System	28 Dec 2020 14:59:39

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '1 Dec 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '11:00'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User entered '1 Dec 2020 11:00'	System	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '171' cm	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21
DataPoint set to visible.	(b) (4) System	28 Dec 2020 14:59:39

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '99.5' kg	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21
DataPoint set to visible.	(b) (4) System	28 Dec 2020 14:59:39

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '36.6' C	Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Oral (Oral)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '76'	Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User entered 'bpm'	System	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '18'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User entered 'breaths/min'	System	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '118'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User entered 'mmHg'	System	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '89'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User entered 'mmHg'	System	28 Dec 2020 15:01:21

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36

US3412118

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36

US3412118

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 15:01:45

US3412118

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '1 Dec 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:01:45

US3412118

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:31:52

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 15:01:55

US3412118

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:31:52

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered '1 Dec 2020'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:01:55

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:37:05

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:37:05

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	06 Jan 2021 20:37:05

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 20:37:05

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 18:21:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:19:55

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
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) (b) (4), (b) (6)	09 Apr 2021 08:46:16
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 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:21:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:21:26
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 18:05:18
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:19:55

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:16:23
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	06 Jan 2021 20:37:36
	(b) (4)	

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:16:23
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	06 Jan 2021 20:37:36
	(b) (4)	

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '1'	System	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'I'	System	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '171.5' cm	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '102.7' kg	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '34.91742'	System	06 Jan 2021 20:39:27
DataPoint set to visible.	System	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '171.5' cm	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '102.7' kg	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '34.91742'	System	06 Jan 2021 20:39:27
DataPoint set to visible.	System	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User accepted default value 'Pre-Dose (PREDOSE)'	Mason Urban (b) (4) (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '11:05'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '6 Jan 2021 11:05'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '36.8' C	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Oral (Oral)'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '88'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'bpm'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '20'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'breaths/min'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '136'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '88'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '171.5' cm	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '102.7' kg	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '34.91742'	System	06 Jan 2021 20:39:27
DataPoint set to visible.	System	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User accepted default value 'Post-Dose (POSTDOSE)'	Mason Urban (b) (4) (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '11:55'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '6 Jan 2021 11:55'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '97.5' F	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Oral (Oral)'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '84'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'bpm'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '20'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'breaths/min'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '132'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '82'	Mason Urban (b) (4)	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	06 Jan 2021 20:39:27

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:39:42

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:39:42

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mRNA-1273'	System	06 Jan 2021 20:40:02
DataPoint set to visible.	System	06 Jan 2021 20:37:36

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '11:22'	Mason Urban (b) (4)	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '6 Jan 2021 11:22'	System	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Left Arm (LEFT ARM)'	Mason Urban (b) (4)	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'ONCE'	System	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 20:40:02

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:40:20

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:40:20

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '11:17'	Mason Urban (b) (4)	06 Jan 2021 20:40:20

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '6 Jan 2021 11:17'	System	06 Jan 2021 20:40:20

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:40:39

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 20:40:39

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:52

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '11:13'	Mason Urban (b) (4)	06 Jan 2021 20:40:39

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:52

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '6 Jan 2021 11:13'	System	06 Jan 2021 20:40:39

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 20:40:47

US3412118

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '1'	System	06 Jan 2021 20:40:47

US3412118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User closed query 'please complete OL-D29 visit CRFs from 3 Feb 2021' (Site from CRA).		07 Apr 2021 20:13:40
Query 'please complete OL-D29 visit CRFs from 3 Feb 2021' answered with 'information has been updated' (Site from CRA).		31 Mar 2021 20:26:53
User opened query 'please complete OL-D29 visit CRFs from 3 Feb 2021' (Site from CRA).		10 Mar 2021 21:45:34
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
	(b) (4)	
User entered 'Yes (Y)'	Mason Urban (b) (4)	13 Jan 2021 17:19:56
	(b) (4)	

US3412118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered '13 Jan 2021'	Mason Urban (b) (4)	13 Jan 2021 17:19:56

US3412118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	13 Jan 2021 17:19:56

US3412118

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered empty.	Mason Urban (b) (4)	13 Jan 2021 17:19:56

US3412118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	13 Jan 2021 17:19:44

US3412118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'I'	System	13 Jan 2021 17:19:44

US3412118

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '1'	System	13 Jan 2021 17:19:44
DataPoint set to visible.	System	13 Jan 2021 17:19:44

US3412118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:44:31

US3412118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:44:31

US3412118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:44:31

US3412118

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'OLD29'	System	25 Mar 2021 15:44:31

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User accepted default value 'Pre-Dose (PREDOSE)'		25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '09:13'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '03 Feb 2021 09:13'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '72'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'bpm'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '22'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'breaths/min'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '144'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '90'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User accepted default value 'Post-Dose (POSTDOSE)'		25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '10:38'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '03 Feb 2021 10:38'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	31 Mar 2021 20:26:27
User entered '36.6' C reason for change: Data Entry Error	System	31 Mar 2021 20:26:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 15:46:54
User entered '36.6' (non-conformant).	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '76'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'bpm'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'breaths/min'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '118'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '72'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	25 Mar 2021 15:46:54

US3412118

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:47:17

US3412118

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:47:17

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mRNA-1273'	System	25 Mar 2021 15:48:10
DataPoint set to visible.	System	13 Jan 2021 17:19:44

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '09:57'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '03 Feb 2021 09:57'	System	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'ONCE'	System	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'INTRAMUSCULAR'	System	25 Mar 2021 15:48:10

US3412118

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:12
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Feb 2021 16:38:39

US3412118

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'I'	System	10 Feb 2021 16:38:39

US3412118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Feb 2021 16:38:51

US3412118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered '10 Feb 2021'	Mason Urban (b) (4)	10 Feb 2021 16:38:51

US3412118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	10 Feb 2021 16:38:51

US3412118

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:52

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered empty.	Mason Urban (b) (4)	10 Feb 2021 16:38:51

US3412118

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:31:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Feb 2021 16:38:57

US3412118

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'I'	System	10 Feb 2021 16:38:57

US3412118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 16:02:28

US3412118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	03 Mar 2021 16:02:28

US3412118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	03 Mar 2021 16:02:28

US3412118

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'OLD57'	System	03 Mar 2021 16:02:28

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '09:08'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '03 Mar 2021 09:08'	System	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '97.3' F	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty.	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '77'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'bpm'	System	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '20'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'breaths/min'	System	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '150'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '92'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered 'mmHg'	System	03 Mar 2021 16:04:13

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36

US3412118

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36

US3412118

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
	System	03 Mar 2021 16:05:08
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	03 Mar 2021 16:04:52
User entered 'No (N)'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:52
	(b) (4)	

US3412118

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 16:05:08
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	03 Mar 2021 16:04:52

US3412118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 16:08:05

US3412118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '03 Mar 2021'	Andrea Newlands (b) (4)	03 Mar 2021 16:08:05

US3412118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
User entered '09:30'	Andrea Newlands (b) (4)	03 Mar 2021 16:08:05

US3412118

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:58:36
User entered '03 Mar 2021 09:30'	System	03 Mar 2021 16:08:05

US3412118

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:31:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:30:34
User closed query 'Per source subject saw cardiologist on 15 Oct 2020 and diagnosed with new onset hyperlipidemia - please confirm with source and add MAAE' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:40:48
Query 'Per source subject saw cardiologist on 15 Oct 2020 and diagnosed with new onset hyperlipidemia - please confirm with source and add MAAE' answered with 'this AE has been put into the AE folder' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 13:43:16
User opened query 'Per source subject saw cardiologist on 15 Oct 2020 and diagnosed with new onset hyperlipidemia - please confirm with source and add MAAE' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 15:08:20
Query 'Per source subject saw cardiologist on 15 Oct 2020 and diagnosed with new onset hyperlipidemia - please confirm with source and add AE' canceled (Site from CRA).		03 Dec 2020 15:06:53
User opened query 'Per source subject saw cardiologist on 15 Oct 2020 and diagnosed with new onset hyperlipidemia - please confirm with source and add AE' (Site from CRA).		03 Dec 2020 15:04:17
User entered 'Yes (Y)' reason for change: Data Entry Error		01 Dec 2020 22:13:32
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	21 Sep 2020 18:11:36

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
Reviewed for Safety.		02 Dec 2020 19:05:52
User entered 'USA-US061-2020-mRNA-1273-P301000015'	System	02 Dec 2020 19:05:47
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 19:05:47

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:52:28
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'hello these underlying risk factors would be listed under the medical history form. there is nowhere to list factors for AE's' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 13:46:11
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:19:19
DataPoint Verified.		03 Dec 2020 14:59:57
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral artery occlusion, LLT: Femoral artery occlusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:48:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:48:02
Data point term sent to Coder	System	01 Dec 2020 22:44:51
User entered 'Right Femoral Artery Occlusion'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'No (N)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'No (N)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered '30 Oct 2020'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:59:57
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Dec 2020 22:45:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Dec 2020 22:45:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 22:45:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Dec 2020 22:44:18
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Dec 2020 22:44:18
User entered 'NA:NA' (non-conformant).	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 22:45:06
User entered '30 Oct 2020 NA:NA' (non-conformant).	System	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'No (N)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered '19 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	01 Dec 2020 22:45:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Dec 2020 22:45:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 22:45:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Dec 2020 22:44:18
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	01 Dec 2020 22:44:18
User entered 'NA:NA' (non-conformant).	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 22:45:41
User entered '19 Nov 2020 NA:NA' (non-conformant).	System	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'Grade 4 (Grade 4)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'Yes (Y)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered '0'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered '0'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 17:20:15
DataPoint Un-verified.		03 Dec 2020 15:00:21
DataPoint Verified.		03 Dec 2020 14:59:57
User entered '19 Nov 2020'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 17:20:17
DataPoint Un-verified.		03 Dec 2020 15:00:23
DataPoint Verified.		03 Dec 2020 14:59:57
User entered '20 Nov 2020'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 17:20:19
DataPoint Un-verified.		03 Dec 2020 15:00:24
DataPoint Verified.		03 Dec 2020 14:59:57
User entered 'Yes (Y)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 17:20:21
DataPoint Un-verified.		03 Dec 2020 15:00:25
DataPoint Verified.		03 Dec 2020 14:59:57
User entered '1'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered '0'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'Not Related (NOT RELATED)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'Not Applicable (NOT APPLICABLE)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered '0'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 17:42:32
User closed 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).		27 Jan 2021 19:52:45
User closed query 'PV Query: Please clarify indication of use for Tamsulosin reported as BPD. Please update indication to BPH if applicable.' (Site from Safety).		27 Jan 2021 19:52:35
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.' answered with 'no con meds are noted in the medical records after the subject procedure. All procedures are listed in con procedures list' (Site from Safety).	Steven Anderson (b) (4)	26 Jan 2021 14:11:50
	(b) (4)	
Query 'PV Query: Please clarify indication of use for Tamsulosin reported as BPD. Please update indication to BPH if applicable.' answered with 'Tamsulosin has been updated to bph.' (Site from Safety).	Steven Anderson (b) (4)	26 Jan 2021 13:47:55
	(b) (4)	
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).	(b) (4), (b) (6)	09 Dec 2020 19:19:51

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify indication of use for Tamsulosin reported as BPD. Please update indication to BPH if applicable.' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:18:54
DataPoint Verified.		03 Dec 2020 15:00:38
User entered '0'		03 Dec 2020 14:59:57
		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
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)	27 Jan 2021 19:52:57
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4)	27 Jan 2021 05:29:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'diagnostic test have been included in con procedures no relevant lab data information' (Site from Safety).	Steven Anderson (b) (4)	26 Jan 2021 14:15:41
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'con procedures form has been filled out' (Site from DM).	Steven Anderson (b) (4)	26 Jan 2021 14:01:58
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 04:22:17
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)	09 Dec 2020 19:19:38
DataPoint Verified.	(b) (4)	03 Dec 2020 14:59:57
User entered 'I'	(b) (4)	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:59:57
User entered empty.		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User closed query 'please consider mentioning anesthesia and perioperative antibiotic details not available' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:06:43
		07 Apr 2021 20:06:28
Query 'please consider mentioning anesthesia and perioperative antibiotic details not available' answered with 'Information has been updated' (Site from CRA). DataPoint Un-verified.		31 Mar 2021 20:08:54
		31 Mar 2021 20:08:49
User entered 'SUBJECT PRESENTED TO HIS PHYSICIAN POST ONSET OF RIGHT LEG CRAMPING AND PAIN ON 30OCT2020. RIGHT FEMORAL ARTERY OCCLUSION WAS DIAGNOSED AND SUBJECT UNDERWENT RIGHT FEMORAL ENDARTERECTOMY ON 19NOV2020. SUBJECT NOTIFIED OUR SITE OF THIS ON 01DEC2020 @10:45AM. SURGERY WAS PERFORMED AT KETTERY MEDICAL CENTER. PROCEDURES PERFORMED: RIGHT COMMON FEMORAL ENDARTERECTOMY WITH PATCH ANGIOPLASTY, RIGHT PROFUNDOPLASTY, RIGHT PROFUNDA THROMBECTOMY, PRAVEENA WOUND VAC RIGHT GROIN. MEDICAL RECORDS WERE RECEIVED AND REVIEWED. ANESTHESIA NOTES WERE REQUESTED. SUBJECT'S HOSPITALIZATION REQUIRE 1 OVER NIGHT ADMISSION. HE WAS RELEASED AND COMPLETELY RECOVERED FROM THE PROCEDURE AND RETURNED TO BASELINE. ANESTHESIA AND PERIOPERATIVE ANTIBIOTIC DETAILS NOT AVAIABLE.' reason for change: Data Entry Error		31 Mar 2021 20:08:49
User opened query 'please consider mentioning anesthesia and perioperative antibiotic details not available' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 17:33:29

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:21:40
DataPoint Un-verified.	Andrea Newlands (b) (4)	02 Mar 2021 16:16:16
User entered 'subject presented to his physician post onset of right leg cramping and pain on 30oct2020. right femoral artery occlusion was diagnosed and subject underwent right femoral endarterectomy on 19nov2020. subject notified our site of this on 01dec2020 @10:45am. surgery was performed at kettery medical center. procedures performed: right common femoral endarterectomy with patch angioplasty, right profundoplasty, right profunda thrombectomy, praveena wound VAC right groin. medical records were received and reviewed. anesthesia notes were requested. subject's hospitalization require 1 over night admission. he was released and completely recovered from the procedure and returned to baseline.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 16:16:16
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)	09 Feb 2021 15:58:24
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)	09 Feb 2021 15:58:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Reviewing medical records no relevant laboratory diagnostic test results documented' (Site from Safety).	Steven Anderson (b) (4)	08 Feb 2021 20:42:14
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 'no COVID-19 testing documented' (Site from Safety).	Steven Anderson (b) (4)	08 Feb 2021 20:41:17

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:54:18
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).		05 Feb 2021 15:54:08
DataPoint Verified.		03 Dec 2020 14:59:57
User entered 'Subject notified us @10:45am 01Dec2020 of his revascularization surgery to his occluded R femoral artery. Subject states his symptoms of R leg cramp and pain began 30Oct2020. He had surgery at Kittering Medical Center on 19Nov2020 and was admitted and observed for 1 night and 1 day (his stay was >24hours). He was released on 20Nov2020.'		01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 22:44:18

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4)	
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'this was not COVID-19 due to negative PCR obtained by site' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 14:45:48
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.'	Steven Anderson (b) (4)	08 Feb 2021 20:43:19
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'this was not COVID-19 due to negative PCR obtained by site' (Site from DM).	(b) (4)	
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:59:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 15:28:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	28 Dec 2020 15:28:20
User entered 'URI'	System	28 Dec 2020 15:27:40
	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '30 Nov 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User entered empty.	System	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User closed query 'Per CDM: Per sponsor review, please confirm if AE is still ongoing. Please update end date and outcome as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 08:04:32
Query 'Per CDM: Per sponsor review, please confirm if AE is still ongoing. Please update end date and outcome as appropriate. Thank you.' answered with 'Information has been updated' (Site from DM).		31 Mar 2021 20:10:04
User entered 'No (N)' reason for change: Data Entry Error		31 Mar 2021 20:09:59
User opened query 'Per CDM: Per sponsor review, please confirm if AE is still ongoing. Please update end date and outcome as appropriate. Thank you.' (Site from DM).		30 Mar 2021 16:02:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '4 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:09:59
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User entered empty.	System	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'I'	Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:09:59
Data Entry Error		
User entered 'Unknown (UNKNOWN)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User entered '0'	System	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02
User entered '1'	System	28 Dec 2020 15:27:06

US3412118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:59:02

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
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.	(b) (4) Coder Import (b) (4)	28 Dec 2020 15:44:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 15:44:20
Data point term sent to Coder	System	28 Dec 2020 15:28:42
User entered 'HYPERLIPIDEMIA'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '15 Oct 2020'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User closed query 'Per CDM: Per sponsor review, please confirm if AE is still ongoing and update end date and outcome as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 08:04:42
Query 'Per CDM: Per sponsor review, please confirm if AE is still ongoing and update end date and outcome as appropriate. Thank you.' answered with 'Information is correct AE is still ongoing at this time (Site from DM).		31 Mar 2021 20:10:48
User opened query 'Per CDM: Per sponsor review, please confirm if AE is still ongoing and update end date and outcome as appropriate. Thank you.' (Site from DM).		30 Mar 2021 16:03:09
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Melissa Fuson (b) (4)	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered 'I'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:09:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:28:35
	(b) (4)	

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 15:28:35

US3412118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:52

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 15:28:35

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:31:52

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 15:01:21
User closed query 'Per hospital records, perioperative antibiotics during revascularization surgery 19 Nov 2020 - please review and consider adding to Con Meds' (Site from CRA).		19 Apr 2021 15:00:58
User closed query 'Anesthesia on 19 Nov 2020? Please consider adding' (Site from CRA).		19 Apr 2021 15:00:36
Query 'Anesthesia on 19 Nov 2020? Please consider adding' answered with 'name of drug unknown at this time' (Site from CRA).		31 Mar 2021 20:17:49
Query 'Per hospital records, perioperative antibiotics during revascularization surgery 19 Nov 2020 - please review and consider adding to Con Meds' answered with 'name of the antibiotics unknown at this time' (Site from CRA).		31 Mar 2021 20:17:18
User opened query 'Anesthesia on 19 Nov 2020? Please consider adding' (Site from CRA).		29 Jan 2021 18:00:05
User opened query 'Per hospital records, perioperative antibiotics during revascularization surgery 19 Nov 2020 - please review and consider adding to Con Meds' (Site from CRA).		29 Jan 2021 17:59:36
User closed query 'please add Crestor to EDC' (Site from CRA).		29 Jan 2021 17:57:15
Query 'please add Crestor to EDC' answered with 'UPDATED EDC CON MEDS FOR CRESTOR' (Site from CRA).	Melissa Fuson (b) (4)	11 Jan 2021 16:50:29
User opened query 'please add Crestor to EDC' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 15:22:00
User entered 'Yes (Y)'		14 Aug 2020 16:41:00

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SODIUM CALCIUM EDETATE, PRODUCTSYNONYM: CALCIUM DISODIUM VERSENATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 16:43:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:43:22
Data point term sent to Coder	System	14 Aug 2020 16:42:32
User entered 'CALCIUM DISODIUM VERSENATE'	(b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'BONE HEALTH'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '600'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:58:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:41:50
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:41:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Aug 2020 10:20:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:20:10
Data point term sent to Coder	System	14 Aug 2020 16:43:35
User entered 'GABAPENTIN'	(b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'HIP AND LEG PAIN'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '400'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:58:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:42:45
User entered 'UN UNK 2016'	(b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:42:45

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User closed query 'Per DM CLR: Pleas review the medication name as the dose seem to reflect a combination medication. Update as appropriate. Otherwise, provide clarification.' (Site from DM). User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HCTZ - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:58:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Query 'Per DM CLR: Pleas review the medication name as the dose seem to reflect a combination medication. Update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM). Coding entries removed.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:30:00
User entered 'LOSARTAN/HCTZ' reason for change: Data Entry Error User opened query 'Per DM CLR: Pleas review the medication name as the dose seem to reflect a combination medication. Update as appropriate. Otherwise, provide clarification.' (Site from DM). 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.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:30:00
	System	26 Oct 2020 18:31:48
	Mason Urban (b) (4) (b) (4)	26 Oct 2020 18:31:07
	Mason Urban (b) (4) (b) (4)	26 Oct 2020 18:30:54
	Mason Urban (b) (4) (b) (4)	26 Oct 2020 18:30:54
	(b) (4), (b) (6)	23 Oct 2020 11:14:43
	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:46:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

2132 of 2425

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Aug 2020 16:46:16
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	14 Aug 2020 16:44:36
User entered 'LOSARTAN'	(b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'HTN'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '100/12.5'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:58:53
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'RECONCILED' (Site from DM).	Mason Urban (b) (4) (b) (4)	26 Oct 2020 18:32:04
User entered 'UN UNK 2018' reason for change: Data Entry Error	Mason Urban (b) (4) (b) (4)	26 Oct 2020 18:30:54
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:15:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:58:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:44:34
User entered 'UN UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:44:34

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 15:55:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 15:55:35
Data point term sent to Coder	System	19 Oct 2020 15:54:29
Coding entries removed.	Mason Urban (b) (4) (b) (4)	19 Oct 2020 15:53:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 23:41:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 23:41:42
Data point term sent to Coder	System	14 Aug 2020 16:45:37
User entered 'MAGNESIUM'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:59:02
User entered 'LEG CRAMPS' reason for change: Data Entry Error	Mason Urban (b) (4) (b) (4)	19 Oct 2020 15:53:58
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	Mason Urban (b) (4) (b) (4)	19 Oct 2020 15:53:40
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:25:23
User entered 'LEG CRAMP'	(b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '250'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'UN Apr 2020' reason for change: Data Entry Error	Mason Urban (b) (4)	19 Oct 2020 15:53:58
	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:58:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:45:12
User entered 'UN UNK 2008'	(b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:45:12

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:18
Data point term sent to Coder	System	14 Aug 2020 16:48:45
User entered 'METOPROLOL'	(b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'HYPERTENSION'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '40'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:58:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:47:59
User entered 'UN UNK 2020'	(b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:47:59

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 16:49:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:49:17
Data point term sent to Coder	System	14 Aug 2020 16:48:46
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '40'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:58:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:48:33
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:48:33

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 09:32:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 09:32:11
Data point term sent to Coder	System	14 Aug 2020 16:49:48
User entered 'PERCOCET'	(b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'HIP AND LEG PAIN'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '100/325'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:58:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:49:08
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 16:49:08

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Jan 2021 13:48:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 13:48:07
Data point term sent to Coder	System	26 Jan 2021 13:47:32
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 13:47:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 08:55:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 08:55:13
Data point term sent to Coder	System	14 Aug 2020 16:49:49
User entered 'TAMSULOSIN'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'BPh' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Jan 2021 13:47:03
	(b) (4)	
User entered 'BPD'	(b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0.4'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:58:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 16:49:36
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 16:49:36

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 16:46:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 16:46:02
Data point term sent to Coder Coding entries removed.	System Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 16:45:05 11 Jan 2021 16:44:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 15:34:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 15:34:20
Data point term sent to Coder User entered 'CRESTOR'	System Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 15:32:48 28 Dec 2020 15:31:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered '20' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered 'mg (mg)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered 'once daily (QD)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	11 Jan 2021 16:44:18
User entered 'UN Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 16:44:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 16:44:18
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 16:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 15:31:50
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 15:31:50
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 16:44:18
User entered empty.	System	28 Dec 2020 15:31:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 16:44:18
User entered empty.	System	28 Dec 2020 15:31:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 16:44:18
User entered empty.	System	28 Dec 2020 15:31:50

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Mar 2021 16:24:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 16:24:43
Data point term sent to Coder	System	02 Mar 2021 16:24:16
User entered 'vitamin d3'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'general health'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered '1000'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'IU (IU)'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered '19 Nov 2020'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	02 Mar 2021 16:24:15
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:24:15

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:24:15

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 16:24:15

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 20:59:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:59:11
Data point term sent to Coder	System	02 Mar 2021 16:28:21
User entered 'hydrocodone'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'hip and leg pain'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '10/325'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'mg (mg)'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 16:29:59
User entered 'once daily (QD)'	(b) (4)	
	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	(b) (4) Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'un UNK 2018'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered '0'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 16:10:31
User entered 'Yes (Y)'	(b) (4)	
	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'un UNK 2020' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 16:10:31
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User entered 'No (N)'	Andrea Newlands (b) (4)	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User entered empty.	System	02 Mar 2021 16:29:59
User entered '1'	System	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User entered empty.	System	02 Mar 2021 16:29:59
User entered '1'	System	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:34:03
User entered empty.	System	02 Mar 2021 16:29:59
User entered '804 (804)'	System	02 Mar 2021 16:27:42

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TEMAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Mar 2021 23:39:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:39:47
Data point term sent to Coder	System	02 Mar 2021 16:30:23
User entered 'temuzepain'	Andrea Newlands (b) (4) (b) (4)	02 Mar 2021 16:29:43

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'hip and leg pain'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered '15'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'un UNK 2018'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:16:32
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	02 Mar 2021 16:29:43
	(b) (4)	

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 16:29:43

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 16:29:43

US3412118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 16:29:43

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:31:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
User closed query 'Please change to yes and add revascularization surgery and any other procedures related to SAE' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:57:00
Query 'Please change to yes and add revascularization surgery and any other procedures related to SAE' answered with 'adding the procedures to the list' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 13:58:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	11 Jan 2021 16:51:07
User opened query 'Please change to yes and add revascularization surgery and any other procedures related to SAE' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 13:23:34
User entered 'No (N)'		14 Aug 2020 16:49:52

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered '19 Nov 2020'	Steven Anderson (b) (4)	26 Jan 2021 13:59:32
	(b) (4)	

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Right common femoral endarterectomy with patch angioplasty'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 13:59:32

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	26 Jan 2021 13:59:32
	(b) (4)	

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered empty.	Steven Anderson (b) (4)	26 Jan 2021 13:59:32
	(b) (4)	

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered '19 Nov 2020'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:02

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Right profundoplasty to the fourth order profunda'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:02

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:02

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:17
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:02

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered '19 Nov 2020'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:35

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'right profunda thrombectomy'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:35

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:35

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:00:35

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered '19 Nov 2020'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:01:05

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'application of praveena wound VAC right groin 13 cm'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:01:05

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:01:05

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:01:05

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered '19 Nov 2020'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:13:36

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'pathology report for right femoral lymph node.'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:13:36

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Diagnostic (DIAGNOSTIC)'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:13:36

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:13:36

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered '19 Nov 2020'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:14:26

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'pathology report for right femoral plaque with atheromatous plaque with calcification'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:14:26

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered 'Diagnostic (DIAGNOSTIC)'	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:14:26

US3412118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:43:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:37:38
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 14:14:26

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:19
Un-reviewed for Safety.		01 Apr 2021 16:15:09
DataPoint Verified.		03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:05
User entered 'USA-US061-2020-MRNA-1273-P301000015'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Richard'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gregory'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Powell'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gottschlich'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '4260 Glendale Milford Road'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Cincinnati'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered 'OH'	System	01 Apr 2021 16:14:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:06:08
User entered '45242'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:55:49
DataPoint Verified.		03 Dec 2020 15:00:08
User entered 'US'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 16:14:46
User entered '3'	System	03 Mar 2021 16:07:57
User entered '2'	System	01 Feb 2021 13:55:46
User entered '1'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4)	01 Apr 2021 16:15:19
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:09
DataPoint Verified.		03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:05
User entered 'USA-US061-2020-MRNA-1273-P301000015'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Richard'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gregory'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Powell'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gottschlich'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '4260 Glendale Milford Road'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:06:08
User entered 'Cincinnati'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered 'OH'	System	01 Apr 2021 16:14:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '45242'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:55:49
DataPoint Verified.		03 Dec 2020 15:00:08
User entered 'US'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 16:14:46
User entered '3'	System	03 Mar 2021 16:07:57
User entered '2'	System	01 Feb 2021 13:55:46
User entered '1'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
User entered '02/Dec/2020 19:06'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:55:49
DataPoint Verified.		03 Dec 2020 15:00:08
User entered '1'		02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4)	01 Apr 2021 16:15:19
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:09
DataPoint Verified.		03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:05
User entered 'USA-US061-2020-MRNA-1273-P301000015'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	03 Dec 2020 15:00:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Richard'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gregory'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Powell'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gottschlich'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '4260 Glendale Milford Road'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Cincinnati'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered 'OH'	System	01 Apr 2021 16:14:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '45242'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:55:49
DataPoint Verified.		03 Dec 2020 15:00:08
User entered 'US'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 16:14:46
User entered '3'	System	03 Mar 2021 16:07:57
User entered '2'	System	01 Feb 2021 13:55:46
User entered '1'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:54
User entered '01/Feb/2021 08:55'	System	01 Feb 2021 13:55:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Feb 2021 13:55:49
User entered '1'		01 Feb 2021 13:55:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4)	01 Apr 2021 16:15:19
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:09
DataPoint Verified.		03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:05
User entered 'USA-US061-2020-MRNA-1273-P301000015'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Richard'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gregory'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Powell'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:06:08
User entered 'Gottschlich'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '4260 Glendale Milford Road'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Cincinnati'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered 'OH'	System	01 Apr 2021 16:14:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered '45242'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:55:49
DataPoint Verified.		03 Dec 2020 15:00:08
User entered 'US'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 16:14:46
User entered '3'	System	03 Mar 2021 16:07:57
User entered '2'	System	01 Feb 2021 13:55:46
User entered '1'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:31:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:54
User entered '03/Mar/2021 11:07'	System	03 Mar 2021 16:07:57

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:31:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered '1'		03 Mar 2021 16:07:57

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4)	01 Apr 2021 16:15:19
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:09
DataPoint Verified.		03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:05
User entered 'USA-US061-2020-MRNA-1273-P301000015'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Yes (Y)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'No (N)'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Richard'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gregory'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered 'Powell'	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Gottschlich'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:06:08
User entered '4260 Glendale Milford Road'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.		02 Dec 2020 19:06:08
User entered 'Cincinnati'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered 'OH'	System	01 Apr 2021 16:14:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 16:15:01
Un-reviewed for Safety.	System	01 Apr 2021 16:14:46
DataPoint Un-verified.	System	01 Apr 2021 16:14:46
User entered empty.	System	01 Apr 2021 16:14:46
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:00:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 19:06:08
User entered '45242'	System	02 Dec 2020 19:05:47

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 13:55:49
DataPoint Verified.		03 Dec 2020 15:00:08
User entered 'US'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 16:14:46
User entered '3'	System	03 Mar 2021 16:07:57
User entered '2'	System	01 Feb 2021 13:55:46
User entered '1'	System	02 Dec 2020 19:06:12

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:31:52

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:54
User entered '01/Apr/2021 12:14'	System	01 Apr 2021 16:14:46

US3412118

Folder: SAE USA-US061-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:31:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:21:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:54
Reviewed for Safety.		01 Apr 2021 16:15:01
User entered '1'		01 Apr 2021 16:14:46